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ST. JUDE MEDICAL

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CMS
2007 SEP 14 P 4:10

Delivered By Hand

September 14, 2007

Kerry Weems, Acting Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20210

Re: CMS-1392-P (Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare and Medicaid Programs: Proposed Changes to Hospital Conditions of Participation; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals)

Dear Mr. Weems:

St. Jude Medical, Inc. welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital outpatient prospective payment systems and calendar year 2008 rates (CMS-1392-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). St. Jude Medical is dedicated to making life better for cardiac, neurological and chronic pain patients worldwide through excellence in medical device technology and services. The company has five major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiac surgery, cardiology, and neuromodulation.

St. Jude Medical understands the complexity of the Hospital Outpatient Prospective Payment System (OPPS) payment methodology and appreciates the considerable effort you and your staff have put into the development of the proposed 2008 OPPS. We also appreciate CMS' commitment to promote stability and appropriate payment for outpatient procedures and services. Payment stability and accuracy in the OPPS takes on even greater importance because the OPPS rates will be used to set ambulatory surgical center (ASC) payments in 2008 and beyond. While we are pleased with some of the proposed changes, we remain concerned with other proposals. Our comments will address several issues raised in the proposed rule including:

- Charge Compression
- Proposed Development of Composite APCs

- Proposed Changes to Packaged Services
- Implantation of Spinal Neurostimulators
- Proposed Payment When Devices Are Replaced with Partial Credit to the Hospital

Charge Compression
("APC Relative Weights")

St. Jude Medical has raised concerns about a bias in the weights commonly known as "charge compression," which has resulted in inaccurate estimates of costs in the outpatient prospective payment system since its implementation in 2000. We believe that adjusting for charge compression is a critical factor to payment accuracy in the OPPS.

Charge compression is the practice of applying a lower percentage markup to higher cost services and a higher percentage markup to lower cost services. These systematic differences in markups within a department have been established as a source of bias in the OPPS weights when the applicable cost-to-charge ratio (CCR) is an average across both low- and high-markup items. MedPAC and others have found that the use of a single departmental CCR results in inaccurate cost estimates, understating the costs of high cost items and overstating the costs for low cost items.

Last year, St. Jude Medical and others recommended that CMS implement a regression-based adjustment to account for charge compression in the inpatient cost-based weights. This methodology was evaluated and validated by RTI International in a CMS-commissioned report to examine this adjustment and other methods to improve the accuracy of Medicare data. The RTI experts agreed that a regression-based statistical adjustment was appropriate and could be implemented quickly. A statistical regression-based adjustment for charge compression would remove the existing bias in the calculation of estimated costs that exists today under the Medicare OPPS. Since the adjustment is applied by CMS to the data used in the calculation, it places no implementation burden on the hospitals.

The proposed rule acknowledges that the RTI study has "obvious importance for both the OPPS and the IPPS,"[1] yet the agency does not propose to implement any of the changes proposed by RTI for CY 2008.[2] Therefore, the payment challenges resulting from charge compression persist, creating inaccurate payments for many APCs related to higher cost devices.

An adjustment to address this long-standing data accuracy problem should not be delayed. The RTI study that CMS commissioned proposed an appropriate adjustment that could be readily implemented without disrupting hospital care, and we believe that CMS

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[1] Federal Register, Vol.72, No.148, page 42641,Thursday, August 2, 2007
[2] Id. at 42643

should follow RTI's expert advice. At a minimum, CMS should adjust for compression in 2008 using a regression-based adjustment in the supplies cost center, where a significant amount of past research and analysis has been completed. Additionally, of all the adjusted CCRs tested by RTI, the largest effect on weights comes from correcting charge compression for devices and implants. Without an adequate adjustment to account for charge compression, the systemic bias that results in inaccurate payment rates will continue, especially for devices and implants.

Proposed Development of Composite APCs *("OPPS: Packaged Services")*

In the proposed rule, CMS states that "defining the 'service' paid under the OPPS by combinations of HCPCS codes for component services that are commonly performed in the same encounter and that result in the provision of a complete service would enable us to use more claims data and to establish payment rates that we believe more appropriately capture the costs of services paid under the OPPS."[3] Further, CMS says that in examination of data for multiple procedure claims it has identified two specific sets of services that it believes are good candidates for payment based on the naturally occurring common combinations of component codes that it sees on the multiple procedure claims – low dose rates (LDR) prostate brachytherapy and cardiac electrophysiologic evaluation and ablation services.

In previous comments, St. Jude Medical noted (and CMS' data support) that it is common for patients with arrhythmias to be evaluated and treated at the same encounter. For example, a diagnostic *electrophysiologic study* (APC 0085) is performed, induced tachycardia(s) are *mapped* (APC 0087), and on the basis of the diagnostic and mapping information, the tissue is *ablated* (APC 0086). Therefore, correctly coded claims would most often include multiple codes for component services that are reported with different CPT codes and that are now paid separately through different APCs. As indicated by the APC panel (March 2007 meeting), there would never be many single claims for these services and those that are reported as single claims would likely represent atypical or incorrectly coded claims. Yet, these correctly coded claims that include multiple services when reported with the same date of service are unusable for ratesetting. Consequently, ratesetting for these services was restricted to relatively few single procedures claims. For example, the 2006 claim data show only 72 single claims out of 11,834 for procedures assigned to APC 0087 (Cardiac Electrophysiologic Recording/Mapping).[4]

St. Jude Medical supports the CMS proposal to establish an encounter-based composite APC for these services that would provide a single payment for certain common combinations of component cardiac electrophysiologic services that are reported on the same date of service rather than to continue to pay for these individual services under

[3] Id. at 42678
[4] Id. at 42681

service-specific APCs. This will enable CMS to use more valid and complete claims data to establish payment rates that more appropriately capture the costs of these combinations of services.

CMS is also proposing to unconditionally package five CPT codes under the grouping of intraoperative services for the CY 2008 OPPS. These codes (93609, 93613, 93621, 93622 and 93623) are all CPT add-on codes that are only reported in addition to the code for the primary procedure. We agree that the data support setting the medians for the composite APC with packaging of the costs of the five intraoperative services. They are supportive dependent services that are provided most often as supplemental to procedures assigned to APCs 0085 and 0086.While the procedures in APCs 0085 and 0086 can be performed without these supportive add-on procedures, the data show that these services are very often reported in the cardiac electrophysiologic evaluation and ablation services.

St. Jude is concerned, however, with the packaging of costs of other items and services proposed to be packaged for the CY 2008 OPPS. For example, CMS is proposing to package payment for certain other "intraoperative" HCPCS codes, specifically those codes that are reported as supportive dependent diagnostic testing or other minor procedures performed during independent procedures. This would include, for example, intracardiac echocardiography (ICE) (CPT 93662), which is reported as an add-on code for cardiac electrophysiology and interventional cardiology procedures that require a transseptal approach. For CPT 93621, 93622, 93651 or 93652, ICE is used to identify the area of the atrial septum where needle puncture can be safely performed. ICE is currently paid separately under APC 0670 with a payment rate of $1,984.52, 48 percent of which is attributed to the catheter.[5] This procedure is a high-cost, low volume procedure offered only in a limited number of hospitals. An analysis of the 2006 claims data show the ICE is reported in approximately 5 percent of the claims involving the above procedures.[6] Additionally, only 14 percent of hospitals that reported CPT 93621, 93622, 93651 or 93652 billed for ICE.[7] We are concerned that packaging this low-volume procedure will contribute inadequately to the medians of the composite APC and to the individual APC medians. Further, the impact of the packaged payment for this supportive procedure will be concentrated in a small subset of hospitals that have invested in this expensive technology. We recommend that this procedure, and similar procedures such as intervascular ultrasound (IVUS) (CPT 92978, 92979, 37250 and 37251), should continue to be paid separately under the OPPS.

CMS has indicated that the proposed composite APCs may serve as a prototype for future creation of more composite APCs, through which OPPS payment could be provided for other types of services in the future. While we believe that this approach has promise where the claims data show that combinations of services are commonly furnished together, we recommend that CMS proceed with caution regarding the application of this

[5] Federal Register, Vol. 68, No. 219, page 65773, Monday, November 15, 2004
[6] Chris Hogan, Direct Research LLC., September 11, 2007
[7] Id.

methodology. Any further development of composite APCs should be accompanied by a clear, transparent process and data for identifying and calculating future composite APCs. Additionally, it is important that composite APCs are designed in a manner that sufficiently accounts for the resources associated with performing the common combinations of services.

Proposed Changes to Packaged Services *("OPPS: Packaged Services")*

CMS is proposing a major change that will extend the current packaging approach to additional services, seeking to improve hospital efficiencies. CMS is specifically proposing to package payment for the following seven categories of supportive ancillary services into the primary diagnostic or treatment procedure with which they are performed:

- Guidance services
- Image processing services
- Intraoperative services
- Imaging supervision and interpretation services
- Diagnostic radiopharmaceuticals
- Contrast agents
- Observation services

While we support CMS' goal to promote more efficient delivery of care, we are very concerned about the proposed packaging of these above services. We believe that there is insufficient time during the 60-day comment period to determine the impact on hospitals on such wide-sweeping changes. Of particular concern is that CMS has not offered a crosswalk to identify where CMS proposes to package the costs of these services. While data needed to fully evaluate the proposal is not available, we expect that the impact of the proposed changes is likely to be significant.

St. Jude Medical is not opposed in principle to the concept of packaging. However, decisions about packaging and bundling payment to promote more efficient delivery of care must be balanced with maintaining payment stability and accuracy.

We specifically address packaging of costs for "intraoperative" services, such as intracardiac echocardiography (ICE) (CPT 93662), under our comments on the proposed development of composite APCs on page 4.

Implantation of Spinal Neurostimulators
(*"OPPS: New HCPCS and CPT Codes"*)

Spinal neurostimulators are used to treat chronic pain and other nervous system disorders. Neurostimulator technology has improved rapidly in recent years, with perhaps the greatest improvement being that the devices are now available with rechargeable batteries. Rechargeable neurostimulators allow more power to be used during therapy, which lets patients be treated with more electrodes and programming options. They also last much longer than the non-rechargeable devices that preceded them. Consequently, rechargeable neurostimulators enhance clinical outcomes for patients who require them while reducing the number of surgeries needed to replace batteries. This provides the patients with more potent therapy and spares them the risks and discomfort of replacement surgery and at the same time lowers the therapy's long-term costs.

CMS granted transitional pass-through payments for rechargeable neurostimulators beginning on January 1, 2006, stating that "By avoiding the need for battery replacement surgery, we believe these data demonstrate that this device is a substantial clinical improvement for the large proportion of patients who receive implantable neurostimulators."[8] Pass-through payments made the more advanced rechargeable technology available to patients who required higher power output while reducing the need for surgical battery replacement. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would have denied patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222. We are concerned that packaging rechargeable neurostimulators into APC 0222 will result in inadequate payment for the more advanced rechargeable technology. As a result, patients who would benefit from rechargeable technology may not receive it, leading to increased replacement surgeries and their associated risks.

St. Jude Medical, Medtronic and Boston Scientific met jointly with CMS on September 7, 2007 to discuss our concerns with the proposed classification of rechargeable neurostimulators for CY 2008. In that meeting, we addressed the issues raised by CMS in the proposed rule regarding the packaging of rechargeable devices into APC 0222 with non-rechargeable predecessor devices. (The presentation is attached for the record.) Our comments below will address each issue discussed in the meeting.

Cost Differential and 2 Times Rule
In the proposed rule, CMS states that a review of CY 2006 claims data for APC 0222

[8] Federal Register, Vol.70, No. 155, page 47359, Friday, August 12, 2005

"shows that the cost of the associated neurostimulator implantation procedures are higher when the rechargeable neurostimulator is implanted rather than the traditional non-rechargeable neurostimulator."[9] In fact, the claims data show that the median costs for implanting rechargeable neurostimulators were nearly $6,500 (56 percent) higher than that of non-rechargeable neurostimulators (see Table 35 below).

Table 35. APC 0222 CY 2006 Data[10]

APC	Claims in APC	No. of hospitals that billed	Pass-edit, non-token, no FB, single billings	Pass-edit, non-token, no FB, median cost ($)
0222	Rechargeable and non-rechargeable combined	868	2,830	12,161.64
0222A	Non-rechargeable only	781	2,412	**11,607.75**
0222B	Rechargeable only	238	422	**18,088.71**

Independent data confirm the significant cost difference between rechargeable and non-rechargeable devices. IMS Health data show that the cost of a rechargeable neurostimulator is $17,980 compared to $11,721 for a non-rechargeable,[11] exclusive of the procedural cost. This suggests that the device cost is compressed in the CMS claims data. It also suggests that even the non-rechargeable device procedure costs may not be covered in APC 0222.

Implantation Costs for Rechargeable and Non-rechargeable Neurostimulators, CMS 2006 Data [12]

APC 0222 Configuration	Median procedure cost ($)	Device portion of cost (83% of total)
0222 with rechargeable neurostimulator	18,089	**15,066**
0222 with non-rechargeable neurostimulator	11,608	**9,668**
Difference	6,481	5,398

Median Average Sales Prices for Rechargeable and Non-rechargeable Neurostimulators, IMS Health CY 2006 Data[13]

Neurostimulator System	Generator ($)	Programmer	Recharger	Total Device Cost ($)
Rechargeable	14,721	1,086	2,173	**17, 980**
Non-rechargeable	10,732	989	NA	**11,721**
Difference				6,260

[9] Federal Register, Vol.72, No. 148, page 42715, Thursday, August 2, 2007
[10] Id. at 42716
[11] IMS Health. Hospital Supply Index of Non-Federal, Short Term Acute Care Hospitals Purchases for Jan 1, 2006-Dec. 31, 2006. Norwalk, Conn.
[12] Federal Register, Vol.72, No.148,page 42716, Thursday, August 2, 2007
[13] IMS Health. Hospital Supply Index of Non-Federal, Short Term Acute Care Hospitals Purchases for Jan 1, 2006-Dec. 31, 2006. Norwalk, Conn.

CMS further states that " the difference in costs [between rechargeable and non-rechargeable procedures] is not so great that retaining the implantation of both types of devices for spinal or peripheral neurostimulation in APC 0222 would cause a 2 times violation, and thereby, justify creating a new clinical APC."[14]

While not representing a violation of the 2 times rule, we believe that the magnitude of the cost difference between rechargeable and non-rechargeable devices could affect hospital behavior and hence beneficiary access to appropriate therapy. A 2 times rule violation should be a sufficient but not a necessary condition for creating a new clinical APC.

In an April 7, 2000 OPPS final rule,[15] CMS noted that other factors, such as resource homogeneity and provider concentration, discussed below, are a consideration in APC classification.

Resource Homogeneity. In the 2000 rule, CMS indicated that "If the procedures within an APC require widely varying resources, it would be difficult to develop equitable payment rates. Aggregated payments to a facility that performed a disproportionate share of either the expensive or inexpensive procedures within an APC would be distorted. Further, the facility might be encouraged to furnish only the less costly procedures within the APC, resulting in a potential access problem for the more costly services."[16]

This would suggest a separate APC for rechargeable neurostimulators. CMS claims data show that there is a substantial variation in facility resources for rechargeable and non-rechargeable implant procedures. Using a combined APC will lead to inequitable payments for both technologies. This may encourage facilities not to furnish clinically appropriate neurostimulators and potentially restrict access for Medicare beneficiaries to rechargeable devices.

Provider Concentration. When discussing provider concentration in the April 2000 rule, CMS states that "If a particular service is offered only in a limited number of hospitals, then the impact of payment for the service is concentrated in a subset of hospitals. Therefore, it is particularly important to have an accurate payment level for services with a high degree of provider concentration." [17]

The previously cited CMS table (Table 35) shows that only 27 percent of hospitals that implanted neurostimulators implanted rechargeable devices in 2006. This concentration of services in a limited number of hospitals increases the importance of having an accurate payment level. The high provider concentration may bias the payment system against the subset of hospitals that provide rechargeable devices.

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[14] Federal Register Vol. 65 No. 68, page 18457, Friday, April 7, 2000
[15] Id. at 18457
[16] Id. at 18457
[17] Id. at 18457

Recent examples where classification of procedures within an APC were determined on criteria other than the 2 times rule include keratoprosthesis and discectomy procedures.[18,19] Although neither procedure violated the 2 times rule, CMS decided that the procedures' costs differed sufficiently enough from items in their original APCs to merit a reclassification.

Coding

Current CPT codes do not distinguish between rechargeable and non-rechargeable implant procedures. In the proposed rule, CMS states that to pay differently for rechargeable neurostimulators would require CMS to " establish one or more Level II HCPCS codes for reporting" and that the creation of such codes is "generally undesirable, unless absolutely essential, because it increases hospital administrative burden as the codes may not be accepted by other payers."[20]

However, special Level II HCPCS G-codes are currently used by CMS to differentiate between other devices or procedures (e.g., defibrillators, stents, and radiosurgery) and do not appear to create an undue burden on hospitals. In any event, for facilities that implant rechargeable neurostimulators, the small administrative burden caused by requiring the use of G-codes is likely to be offset by receiving adequate payment for rechargeable neurostimulators.

Alternatively, the administrative burden of using G-codes could be eliminated entirely by using existing C-codes with existing CPT codes to assign rechargeable and non-rechargeable procedures to separate APCs. This option would eliminate the need for new codes. Hospitals are already required to report C-codes with CPT codes when billing for the insertion of neurostimulators. Thus, this option would not represent any change in coding requirements and would create no increased hospital administrative burden. The proposed composite APCs demonstrate CMS' ability to assign procedures to APCs based on combinations of codes.

Packaging

CMS has also questioned the establishment of separate payments for rechargeable neurostimulators at a time when it is proposing to increase packaging under the OPPS through expanded payment groups. While the packaging of supportive ancillary services with a primary procedure may lead to increased efficiency, rechargeable and non-rechargeable neurostimulators represent alternative treatments depending on patient needs. Neither treatment is a subordinate, supportive, or optional service to the other. Packaging neurostimulator technologies will result in substantial underpayment and could hinder access to rechargeable devices. This will lead to less efficiency when

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[18] Federal Register Vol.71, No. 226, page 68053, Friday, November 24, 2006
[19] Federal Register Vol.69, No. 219, Monday, November 15, 2004
[20] Federal Register, Vol.72, No.148, page 42715, Thursday, August 2, 2007

patients are not able to receive rechargeable technology and therefore may require increased battery replacement surgeries.

Product Mix

In the rule rule, CMS states, "To the extent that the rechargeable neurostimulator may become the dominant device implanted over time for neurostimulation, the median costs of APCs 0222 and 0039 would reflect the change in surgical practice in future years."[21] However, rechargeable spinal cord neurostimulators accounted for approximately 15 percent of the procedures in APC 0222 in 2006. While it is true that the use of rechargeable technologies is expected to grow incrementally, APC 0222 is likely to remain mostly composed of non-rechargeable devices. Non-rechargeable spinal cord neurostimulators represented approximately 26 percent of the procedures in APC 0222 in 2006. Multiple other non-rechargeable technologies (i.e., sacral nerve, gastric nerve, and peripheral nerve neurostimulators) represented the remaining 60 percent of the procedures in APC 0222. These therapies lack an approved rechargeable alternative. Therefore, even as the use of rechargeable spinal cord neurostimulators grow, they will not become the dominant device implanted in APC 0222. Rechargeable devices are unlikely to substantially influence the APC's median cost in the near term, especially if inadequate payment limits patient access to rechargeable devices.

Efficiency

According to CMS, the standard practice of placing technologies coming off pass-through status into the APC with its predecessor device encourages hospitals to use resources more efficiently. Yet in the case of rechargeable neurostimulators, this practice is likely to produce long-term inefficiencies. The proposed packaging may encourage facilities to implant less costly but short-lived non-rechargeable devices in patients with complex pain patterns. This could lead to higher long-term costs as non-rechargeable devices are replaced. Creating two APCs now will promote efficiency by reducing the number of replacement procedures.

Comparable Treatment Across APCs

CMS asks how rechargeable device implantation differs from other scenarios where "general HCPCS codes describe procedures that may utilize a variety of devices with different costs, and payment for those devices is packaged into the payment for the associated procedures."[22] There are several differences between rechargeable device implantations and other scenarios. First is the magnitude of the cost differences between items in APC 0222. We are not aware of other APCs that have a difference of nearly $6,500. This is likely to affect hospital acquisition of, and patient access to, rechargeable devices, particularly when underlying payment appears inadequate even for non-rechargeable therapy. And unlike other OPPS services, rechargeable neurostimulators can reduce long-term costs by reducing the number of battery replacement procedures.

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[21] Id. at 42715
[22] Id. at 42715

St. Jude Medical urges CMS to create a new APC for implanting rechargeable neurostimulators for CY 2008. This will ensure that the costs of rechargeable devices are sufficiently recognized to ensure rather than limit or reverse beneficiary access in the OPPS. Additionally, patients who have higher power needs would receive the advantages of rechargeability and face fewer battery replacement surgeries, which in turn would reduce their long-term cost of care. This is consistent with CMS' goal of improving efficiency and enhancing value.

Proposed Payment When Devices Are Replaced with Partial Credit to the Hospital ("OPPS: Device-Dependent APCs")

In the 2007 OPPS final rule, CMS adopted a policy that reduces the APC payment to a hospital for selected device-dependent APCs when the hospital receives replacement devices without costs or receives a full credit for the device being replaced. The CY 2007 reduction policy does not apply to cases in which there is partial credit toward the replacement of the device. For 2008, CMS proposes to expand the policy to require hospitals to report occurrences of devices being replaced under warranty or otherwise with a partial credit granted to the hospital.

CMS proposes to create a HCPCS modifier that would be reported in all cases in which the hospital receives a partial credit toward the replacement of one of the 31 medical devices listed in Table 39 of the proposed rule. CMS proposes to reduce the payment for the APC into which the device costs is packaged by one-half the amount of the offset that would apply if the device were being replaced without cost or with full credit when the amount of the device credit is at least 20 percent of the costs of the new replacement device being implanted.

Under the inpatient policy adopted in the 2008 final rule, CMS only applies the reduced payment to cases in which the hospital receives a credit equal to 50 percent or more of the cost of the device. This ensures that the reduction in payment does not occur when the credit is nominal or relatively inconsequential in comparison to the overall payment for the case. CMS should raise the proposed threshold from 20 percent to 50 percent in the final OPPS rule as is the case under the IPPS.

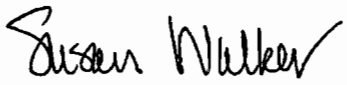
We share CMS' concern that requiring hospitals to reduce their charges in proportion to the partial credit or to provide paper invoices or other information to the fiscal intermediary (or Medicare administrative contractor) indicating the hospital's normal cost of the device and the amount of the credit received may impose an administrative burden on hospitals. Thus, we urge CMS to exclude any such requirements in the final rule. However, we encourage CMS to work with hospitals to develop the least burdensome approach to incorporate reductions based on empirical data.

We are concerned about the potential for payment delays that could occur while a returned device is being evaluated during a warranty service period. The process proposed by CMS would require that claims be suspended or held by the hospital until credit information was received from the manufacturer. While this typically would not present a problem in the case of a known recall, the determination of warranty status typically requires 6 weeks or more following the return of the device to the manufacturer, as most devices require laboratory analysis. During this time, the hospital would be unaware whether a full, partial, or even zero credit would be made. Thus, claims could be suspended or held by the hospital for more than 45 days, which would create administrative and financial burdens for hospitals. In the 2008 final inpatient rule, CMS acknowledged the validity of similar concerns and agreed that hospitals should have the options of either: 1) submitting the claims immediately without the special condition code (Condition Code 49 under the IPPS) and then submitting a claim adjustment with the condition code at a later date once the credit determination is made, or 2) holding the claim until a determination is made on the level of the credit. St. Jude Medical believes that CMS should give hospitals the same options for reporting the HCPCS modifier under the OPPS.

Conclusion

St. Jude Medical appreciates the opportunity to offer these comments. We look forward to working with CMS on these and other issues of concern in the future. If you have any questions, please contact me directly at 651-481-7638 or at swalker@sjm.com.

Sincerely,



Susan Walker
Senior Director, Health Policy and Reimbursement

Outpatient Hospital Reimbursement for Neurostimulators: OPPS Proposed Rule

Boston Scientific, Medtronic, & St. Jude Medical Meeting with CMS
September 7, 2007

1

Agenda

- Packaging of Rechargeable Neurostimulator Implants into APC 0222
- Review of Rechargeable Neurostimulator Technology and Clinical Benefit
- Issues Raised in Proposed Rule
- Recommendations

2

OPPS Actions on Rechargeable Neurostimulators

- Rechargeable neurostimulator implants approved for pass-through payment in 2006-2007
- Pass-through payment to be discontinued in 2008
- Companies requested distinct coding and separate APC for rechargeable neurostimulators
- 2008 proposed rule packaged rechargeable neurostimulators into APC 0222 "*Implantation of Neurological Device*" with predecessor non-rechargeable device

Concerns with OPPS Proposal

Proposed packaging in 2008 will result in inadequate hospital payment for more advanced rechargeable technology → Patients who would benefit from rechargeable technology may not receive it, leading to increased replacement surgeries and associated risks

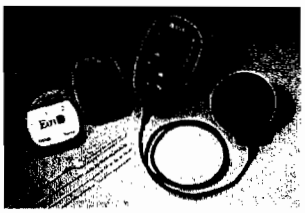
3

Recommendations

- Distinct APCs based on rechargeability
  - Create new APC for implantation of rechargeable pulse generators for spinal cord (SCS) and peripheral nerve stimulation (PNS)
  - Retain APC 0222 for implantation of non-rechargeable pulse generators or receivers
- Adopt separate coding structure for rechargeable neurostimulators
  - C codes or G codes

4

Rechargeable Neurostimulator Technology



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Key Benefits of Rechargeable Neurostimulation Technology

- Advanced power source and functionality
  - Recharges safely and repeatedly through the skin wirelessly
  - Stimulates multiple, non-contiguous pain areas with more electrodes and programming options
- Higher power output to optimize pain relief
  - Meets the high energy demands of complex pain
  - Alleviates major problem in clinical practice of having to manage battery life rather than patient's chronic pain
  - Reduces the need for surgical battery replacement
- Increased compliance with treatment protocol
  - Eliminates physician need to compromise pain relief settings or turn stimulation off to preserve battery life
  - Greatly improves patient compliance over medication therapy

6

Battery Life Managed at the Expense of Pain Relief

Spinal Cord Stimulator Adjustment to Maximize Implanted Battery Longevity: A Randomized, Controlled Trial Using a Computerized, Patient-Interactive Programmer

Richard B. North, MD*,†, ▪ David D. Brigham, BS†, ▪ Alexander Khalessi, MS*, ▪ Sherri-Kae Calkins‡,§, ▪ Steven Plantadosi, MD, PhD¶, ▪ David S. Campbell, BS†, ▪ Michael John Daly, MD‡, ▪ P. Bobby Dey, MD‡, ▪ Giancarlo Barolat, MD§, ▪ Rod Taylor, PhD MSc**

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Neuromodulation, Volume 7, Number 1, 2004 13–25

7

Patient Benefit from Reduced Replacement Procedures

- Reduction in commonly cited complications (low occurrence in general)
  - Infection
  - Seroma
  - Pain over implant
  - Allergic reaction
  - Hardware malfunction
  - Battery failure
  - Skin erosion

Turner JA, Loeser JD, Deyo, RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain*, 2004; 108: 137-147

Cameron, T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *Journal of Neurosurgery: Spine*, 2004; Volume 100: 254-267

Follett KA, Boortz-Marx RL, Drake JM, DuPen S, Schneider SJ, Turner MS, Coffey RJ. Prevention and Management of Intrathecal Drug Delivery and Spinal Cord Stimulation System Infections. *Anesthesiology*, 2004; V 100, No 6; 1582-1594

8

Conditions That Led to Pass-Through Approval Still Hold True

- Device demonstrates substantial clinical improvement
- Cost of device is "not insignificant"
- Proposed APC 0222 not appropriate for rechargeable technology

9

Neurostimulator Cost Findings from 2008 Proposed Rule

"Review of our CY 2007 claims data for APC 0222 shows that the cost of the associated neurostimulator implantation procedures are higher when the rechargeable neurostimulator is implanted rather than the traditional non-rechargeable neurostimulator."

OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42715 [emphasis added]

TABLE 35.—APC 0222 CY 2006 DATA BASED ON CLAIMS REPORTING DIFFERENT NEUROSTIMULATOR DEVICES

APC 0222 configurations	CY 2006 count of hospitals billing	CY 2006 pass edit, nonzero, no FB single bills	CY 2006 pass edit, nonzero, no FB median cost
APC 0222, including claims with both rechargeable and nonrechargeable neurostimulators ...	968	2,930	$12,161.64
APC 0222A, including only claims with nonrechargeable neurostimulators	781	2,412	11,607.79
APC 0222B, including only claims with rechargeable neurostimulators	238	422	18,088.71

- Procedures with rechargeable devices are $6,500, or 56%, greater than with non-rechargeable

10

Issues Raised By CMS in 2008 Proposed Rule

1. Cost Differential and 2-Times Rule
2. Coding
3. Increased Packaging
4. Product Mix
5. Efficient Use of Resources
6. Comparable Treatment Across APCs

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1 2 Times Rule Not Only Reason to Split APCs

CMS: "..the difference in costs [between rechargeable and non-rechargeable devices] is not so great that retaining the implantation of both types of devices for spinal and peripheral neurostimulation in APC 0222 would cause a 2 times violation, and thereby, justify creating a new clinical APC."[1]

- 2 times violation should be a <u>sufficient</u> but <u>not a necessary condition</u> for splitting APCs
- Rechargeable neurostimulators have a substantial cost difference compared to non-rechargeable neurostimulators
- Claims data underestimate the cost of rechargeable neurostimulators
- Magnitude of cost differential could affect hospital behavior and hence beneficiary access to most appropriate therapy

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[1]OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42715

Independent Data Confirm Cost Differences Between Rechargeable and Non-Rechargeable Neurostimulators

- CMS data demonstrate substantial cost differential in APC 022 between median costs of rechargeable and non-rechargeable device procedures.
- IMS ASP data confirm significant differences in the ***device costs*** of rechargeable and non-rechargeable devices.

APC 0222 Configurations	CY 2006 Median Procedure Cost	Device Portion (83.29%)
APC 0222 - with rechargeble neurostimulators	$18,089	$15,066
APC 0222 - with nonrechargeable neurostimulators	$11,608	$9,668
Difference	$6,481	$5,398

Neurostimulator System	Median CY 2006 Average Sales Price[1]			
	Generator	Programmer	Recharger	Total Device Cost
Rechargeable	$14,721	$1,086	$2,173	$17,980
Non Rechargeable	$10,732	$989	NA	$11,721
			Difference	$6,260

- Differences in device cost underestimated in claims data relative to IMS data
- Suggests even *non-rechargeable* device procedure costs may not be covered in APC 0222

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[1] IMS HEALTH, Hospital Supply Index of non-federal, short-term acute care hospital purchases for Jan 1, 2006 - Dec 31, 2006, median average sales price

Criteria for Evaluating Changes to APCs

- In addition to 2 times rule, factors taken into consideration in APC classification:[1]
  - Resource homogeneity
  - Clinical homogeneity
  - Provider concentration
  - Frequency of service
  - Minimal opportunities for upcoding and code fragmentation

[1]OPPS Final Rule, Federal Register, April 7, 2000, pp.18457-58

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Resource Homogeneity Suggests Separate Classification of Rechargeables

"The amount and type of facility resources ... that are used to furnish or perform the individual procedures or services within each APC should be homogeneous...

"If the procedures within an APC require widely varying resources, it would be difficult to develop equitable payment rates....

"Aggregated payments to a facility that performed a disproportionate share of either the expensive or the inexpensive procedures within an APC would be distorted...

"Further, the facility might be encouraged to furnish only the less costly procedures within the APC, resulting in a potential access problem for the more costly services...[1]

- Claims data show clear, substantial variation in facility resources for rechargeable and non-rechargeable device procedures
- One combined APC leads to inequitable payment for both technologies
- May encourage facilities not to furnish clinically appropriate devices, resulting in potential access problem for Medicare beneficiaries

[1]OPPS Final Rule, Federal Register, April 7, 2000, p.18457 [emphasis added]

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Provider Concentration

"If a particular service is offered only in a limited number of hospitals, then the impact of payment for the service is concentrated in a subset of hospitals.

"Therefore, it is particularly important to have an accurate payment level for services with a high degree of provider concentration."[1]

- Only 27% of hospitals that implanted neurostimulators implanted rechargeable devices in 2006

TABLE 35.—APC 0222 CY 2006 DATA BASED ON CLAIMS REPORTING DIFFERENT NEUROSTIMULATOR DEVICES

APC 0222 configurations	CY 2006 count of hospitals billing	CY 2006 pass edit, nontoken, no FB single bills	CY 2006 pass edit, nontoken, no FB median cost
APC 0222, including claims with both rechargeable and nonrechargeable neurostimulators ...	868	2,830	$12,161.64
APC 0222A, including only claims with nonrechargeable neurostimulators ...	781	2,412	11,607.75
APC 0222B, including only claims with rechargeable neurostimulators ...	238	422	18,068.71

- Concentration of providers limits volume now available to affect recalibration of weights; may lead to inequitable payment for implanting centers

[1]OPPS Final Rule, Federal Register, April 7, 2000, p.18457

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APC Reclassifications Where Factors Other Than 2-Times Rule Considered

- Keratoprosthesis: Created APC 0293 after transitional pass-through payment expired
  - Median cost for keratoprosthesis ($3,177) vs. lowest cost procedure ($1,931) not a 2-times violation ($1,246, 1.65)[1,2]
  - CMS concluded "persistent small contribution to the median cost" likely and APC reassignment merited "to pay more appropriately for procedure and related device."[1,2]
- Discectomy: Reassigned from APC 0220 to APC 0221[3]
  - Median cost for discectomy ($1,919) vs. lowest procedure ($1,013) in old APC not a 2-times violation ($906, 1.89)
  - "[We] find resource costs for CPT code 62287 may be more appropriate for APC 0221...Therefore, we have reassigned CPT code 62287 to APC 0221"[3]

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[1] http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms1506fc.pdf
[2] http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/CMS1506FC_HCPCS_Code.zip
[3] Federal Register/Vol. 69, No. 219/November 15, 2004; Changes to the Hospital Outpatient Propsective Payment System and Calendar Year 2005 Payment Rates

❷ Coding Available to Distinguish Rechargeable Technology

CMS: "In addition, to pay differentially would require us to establish one or more Level II HCPCS codes for reporting under the OPPS..."

"The creation of special Level II HCPCS codes for OPPS reporting is generally undesirable, unless absolutely essential, because it increases hospital administrative burden as the codes may not be accepted by other payers."[1]

- Paying separately for rechargeable technology will require unique identification of rechargeable devices
- Coding burden on hospitals can be minimized

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[1] OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42715

Coding Options

- Existing C Codes
  - Use existing C codes combined with existing CPT codes to assign APCs
- New G Codes
  - Create two new HCPCS II "G" codes to differentiate between insertion/replacement of rechargeable and non-rechargeable generators

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APC Structure Under Proposed Coding Options

Existing C Codes and CPT Codes

APC	APC Description	CPT Code	C Code
0222	Implantation of neurological device, non-rechargeable	63685[1]	C1767
		64590[2]	C1767
New Rechargeable APC	Implantation of neurological device, rechargeable	63685[1]	C1820
		64590[2]	C1820

New G Codes

APC	APC Description	HCPCS II Code	HCPCS II Code Description
0222	Implantation of neurological device, non-rechargeable	GXXXX	Insertion or replacement of spinal, peripheral, or gastric neurostimulator pulse generator or receiver, non-rechargeable
New Rechargeable APC	Implantation of neurological device, rechargeable	GYYYY	Insertion or replacement of spinal, peripheral, or gastric neurostimulator pulse generator or receiver, rechargeable

[1]CPT 63685 Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
[2]CPT 64590 Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling

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Coding Rationale

- C Codes
  - C codes currently exist; would not require issuing new codes
  - Hospitals already use the neurostimulator C codes and will continue to be required to do so in the future, thus no change in coding whatsoever
  - Simplest to implement and administer
- G Codes
  - Currently used by CMS to differentiate between other device types, eg. defibrillators, stents, radiosurgery
  - Consistent with previous CMS actions to identify and pay separately for distinct Medicare services
  - Based on feedback from implanting centers, would not appear to create undue burden on hospitals

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❸Distinct Treatment of Rechargeable Devices Is Not An Issue of Packaging

CMS: "Establishing separate coding and payment would reduce the size of the APC payment groups in a year where we are proposing to increase packaging under the OPPS through expanded payment groups."[1]

- The goal of increased packaging is to increase efficiency and allow hospitals maximum flexibility to manage their resources.[2]
- Packaging of ancillary services is a worthy goal to increase efficiency.
- Rechargeable and non-rechargeable stimulators represent alternative treatments depending on patient needs; neither is a subordinate, supportive or optional service to the other.
- Combining neurostimulator technologies would result in underpayment and could hinder access to rechargeable devices.
- Contrary to efficiency, beneficiaries not able to receive rechargeable technology may undergo increased replacement procedures and associated costs.

[1]OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42715
[2]OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42677

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❹ Product Mix Unlikely to Improve Future Rates for Rechargeable Devices

CMS: "To the extent that the rechargeable neurostimulator may become the dominant device implanted over time for neurostimulation, the median costs of APCs 0222 and 0039 would reflect the change in surgical practice in future years."[1]

- Rechargeable spinal cord neurostimulators are an important new class of technologies, accounting for approximately 15% of procedures in APC 0222 in 2006 (though usage expected to grow incrementally)
- Non-rechargeable spinal cord neurostimulators represent approximately 26% of procedures in APC 0222 in 2006
- Multiple other neurostimulation technologies assigned to APC 0222 represent the remaining 60% of procedures in APC 0222
  - Sacral nerve neurostimulators (non-rechargeable)
  - Gastric nerve neurostimulators (non-rechargeable)
  - Other peripheral nerve neurostimulators (non-rechargeable)
- Even as rechargeable SCS grows, share in APC 0222 would not be dominant
- Rechargeable devices likely to contribute inadequately to median cost in future years, especially if proposed payment limits patient access and utilization of the technology

[1]OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42715

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❺ Creating Two APCs Would Improve Efficiency Over Long-Term

CMS: "...[W]ith the rechargeable neurostimulator coming off pass-through status for CY 2008, by following our standard practice we would be increasing the size of APC 0222 and APC 0039 bundles for CY 2008, thereby encouraging hospitals to use resources most efficiently."[1]

- Proposed packaging creates incentives to minimize procedure costs at expense of longer term efficiency.
- Under proposed APC structure, payment rates for rechargeable neurostimulators are substantially less than device and procedure costs.
- Proposed packaging may encourage hospitals to implant less costly but shorter-lived non-rechargeable devices in patients with complex pain patterns because of financial disincentives to use rechargeable neurostimulators.
- Future replacement of non-rechargeable devices in such patients will lead to higher long-term costs.
- Creating two APCs will encourage long-term efficiency by reducing future replacement procedures.

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[1]OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42715

❻ Other OPPS Scenarios Not Similar to Rechargeable Neurostimulators

> CMS: "...[W]e request that commenters address how this specific device implantation situation differs from many other scenarios under the OPPS, where relatively general HCPCS codes describe procedures that may utilize a variety of devices with different costs, and payment for those devices is packaged into the payment for the associated procedures."[1]

- We are unaware of other APCs where magnitude of cost difference among packaged services is as substantial as proposed for neurostimulators.
- $6,500 discrepancy in costs likely to affect hospital acquisition and patient access for rechargeable technology
  - ...Particularly when underlying payment appears inadequate even for non-rechargeable therapy
- Unlike many other services, implantation of rechargeable neurostimulators increases long-term efficiency by reducing future replacement procedures.

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[1]OPPS Proposed Rule, Federal Register, Aug 2, 2007, p. 42716

Many Reasons to Split APCs for Rechargeable Technology

Cost Differential and 2-Times Rule	Significant cost differential ($6,500, 56%) Resource homogeneity Provider concentration/equitable payment Comparable precedents	✔
Coding	No additional coding burden on hospitals	✔
Increased Packaging	Combining neurostimulator technologies would result in underpayment & could hinder access to rechargeable devices	✔
Product Mix	Rechargeable devices not likely to contribute to median cost in future years, especially if proposed payment limits patient access and utilization of the technology	✔
Efficient Use of Resources	Creating two APCs will encourage long-term efficiency by reducing future replacement procedures	✔
Comparable Treatment Across APCs	Other OPPS scenarios are not similar to rechargeable neurostimulator scenario	✔

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Recommendations

- Distinct APCs based on rechargeability
  - Create new APC for implantation of rechargeable pulse generators for SCS and PNS
  - Retain APC 0222 for implantation of non-rechargeable pulse generators or receivers
- Adopt separate coding structure for rechargeable neurostimulators
  - C codes or G codes (as described above)

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Expected Outcome

- The proposed recommendations will ensure that the costs of rechargeable devices are recognized sufficiently to ensure rather than limit or reverse beneficiary access in the OPPS.
- Patients would receive the advantages of rechargeability, rather than face additional surgeries.
- CMS would experience the savings that the technology is producing
- Consistent with CMS goal to "improve efficiency and enhance value."
- Ensuring adequate payment in OPPS will prevent magnification of issue in the ASC.

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Discussion

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Back-Up Slides

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Rechargeable Neurostimulator Costs "Not Insignificant"

- The estimated averaga reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service associated with the category of devices

Data Source	Total Rechargeable Neurostimulator Cost[1]	Proposed CY 2008 APC 0222 Payment	% Exceeded of APC Payment
IMS HEALTH	$17,980	$12,314	46%
CMS CY 2006 Claims	$15,066	$12,314	22%

- The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the service associated with the category of devicas by at least 25 percent.

Data Source	Total Rechargeable Neurostimulator Cost[1]	Device Related Portion of APC 0222	% Exceeded of Device Related Portion
IMS HEALTH	$17,980	$10,256	75%
CMS CY 2006 Claims	$15,066	$10,256	47%

- The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment.

Data Source	Median Average Cost of Devices[1]	Device Related Portion of APC 0222	Difference	Proposed CY 2008 APC 0222 Payment	% of APC Payment
IMS HEALTH	$17,980	$10,256	$7,724	$12,314	63%
CMS CY 2006 Claims	$15,066	$10,256	$4,810	$12,314	39%

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[1] IMS HEALTH, Hospital Supply Index of non-federal, short-term acute care hospital purchases for Jan 1, 2006 - Dec 31, 2006, median average sales price

Advanced Power Source & Functionality

Rechargeable System Attributes

- Rechargeable, fully implantable
- Increased number of electrodes
- Increased programming capabilities
- Physician prescribed, patient selectable electrode configurations
- Advanced diagnostics and data storage

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More Responsive Therapy for Patients with Complex Pain

- Ability to increase parameters to meet the needs of the high energy demands of complex pain
- Flexibility of programs to meet the demands of complex pain patterns
- Increased compliance with treatment regimen

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Substantial Clinical Improvement

- CMS determined that rechargeable technology met the substantial clinical improvement criteria under IPPS and OPPS
  - *"By avoiding the need for battery replacement surgery, we believe these data demonstrate that this device is a substantial clinical improvement for a large proportion of the patients who receive implantable neurostimulators."* [1]
  - *"Because of the elimination of the need for serial battery replacement surgeries, and in light of the information provided by the manufacturer and comments further clarifying the distinctions and improvement of the Restore® technology when compared to other devices, we believe that the device is a substantial clinical improvement over prior technologies."*[1]
  - *Commenters reported "rechargeable neurostimulators have allowed a significant advance to the field of neuromodulation for treatment of chronic intractable pain."*[2]

[1]Federal Register Vol 70, No. 155/Friday, August 12, 2005, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Final Rule.
[2]2006 Final OPPS Rule, p. 426

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Both Rechargeable and Non-Rechargeable Devices Will Continue to Be Used, Based on Patient Need

Pain Classification	Unilateral	Bilateral	Complex
Associated Indications	Single limb pain CRPS	FBS CRPS-2 Radiculopathies Arachnoiditis Peripheral neuropathy	CRPS-1 FBS Radiculopathies Arachnoiditis
Characteristics	Monoradicular stable	Stable bifocal	Multifocal, progressive, complex symptoms, more dermatomes involved, pain pattern changes with postural changes, mixed origin
Systems to Consider	Single Channel Device	Dual Channel Device	Rechargeable Device

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UNIVERSITY OF COLORADO
HOSPITAL
ANSCHUTZ MEDICAL CAMPUS

September 7, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P or CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

The University of Colorado Hospital respectfully submits the attached comments to the 2008 Proposed OPPS Rule published in the August 2, 2007 Federal Register. We appreciate the opportunity to provide you with this information and hope you find it beneficial as you finalize the rule.

Sincerely,

Nancy Prade

Nancy Prade, MBA, RHIA
Director, Health Information Management
University of Colorado Hospital
Mail Stop A025
P.O. Box 6510
Aurora, CO 80045

Comments to CMS – 1392P
42 CRF Part 410, 411, 414 et al
Medicare and Medicaid Programs: CY 2008 Proposed changes Proposed Rule

II. Proposed Updates Affecting OPPS Payments

OPPS Proposed Packaging Approach

Background:

CMS is proposing to package different services that would be paid under bundles. CMS proposes to package the payment for HCPCS codes describing certain ancillary services into the primary diagnostic or treatment procedure with which they are furnished. The APC payment rate would be increased to capture the additional cost of the proposed packaging. In the proposed rule CMS has listed seven categories to extend the packaging approach:

1. Guidance services – All MR, CT, ultrasound, and stereotatic guidance would be bundled into the needle placement, biopsy or various other procedural codes where guidance is usually associated.
2. Image processing services – 3-D post processing (CPT code 76376 and 76377) will not be paid separately, but will be considered packaged into whichever services are affiliated with their use.
3. Intraoperative services – Codes that are reported for supportive dependent diagnostic testing or minor procedures performed during independent procedures (intraoperative neurological testing or intraoperative ultrasound).
4. Imaging supervision and interpretation services – HCPCS codes (77240, 75671, and 93555 to name a few) will all be packaged into their primary procedural codes in addition to packaging the contrast.
5. Diagnostic radiopharmaceuticals – CMS currently packages payment for diagnostic radiopharmaceuticals with a per day cost of $55 or less. CMS proposes for CY 2008 that all diagnostic radiopharmaceuticals are an ancillary service that is supportive of the diagnostic test being performed.
6. Contrast Media – Under current CY 2007 CMS currently packages contrast media with a per day cost of $55 or less. CMS proposes for CY 2008 that all contrast media should be packaged as it is an ancillary service that is supportive of the diagnostic test being performed.
7. Observation services

Comment:

We respectfully submit our disagreement with the proposed packaging guidelines. CMS currently pays each component (CPT/HCPCS) separately depending upon the APC group and payment rate set for that group. Although CMS is proposing to increase the APC payment rate of the primary procedure or treatment, codes that were payable in the past now are packaged (SI "N"), which will create an adverse financial impact for hospitals. We believe CMS has taken a step backwards by proposing to package all observation services, including those that CMS once made a separate APC payment based on criteria (see example below). Facilities do incur additional resources when a patient is admitted

to observation. The proposed increase of the APC reimbursement rate for the emergency room patient ($23.55) does not adequately cover the resource expense in providing efficient quality care in patients requiring observation.

Observation

HCPCS Code	Short Descriptor	Sum of 2007 Payment (Some G0378 Paid Separately)	Sum of 2008 Proposed Payment (G0378 Packaged)
G0378 (under criteria for separately paid observation care)	Hospital observation per hr (dependent service)	$442.81	$0.00
99285	Emergency dept visit	$325.26	$348.81
Total Payment		**$768.07**	**$348.81**

Another example of the proposed packaging methodology impacts imaging supervision and interpretation (S & I). By proposing to package the S & I service along with the contrast media for CY 2008, the emergency room visit is absorbing the APC reimbursement responsibility for all services provided to the patient (see below). We also want to comment that the APC payment would further be reduced if the patient visited an outpatient clinic and HCPHS code 99214 (outpatient office visit) was substituted for code 99285 (emergency room visit). The payment rate for code 99214 is $84.87.

Emergency Room with S & I Example

HCPCS Code	Short Descriptor	Sum of 2007 Payment (72240 Paid Separately)	Sum of 2008 Proposed Payment (72240 Packaged)
62284	Injection for myelogram (dependent service)	$0.00	$0.00
Q9947*	LOCM 200-249mg/ml iodine, 1ml (dependent service)	$64.24	$0.00
72240	Myelogram cervical S&I	$157.01	$0.00
99285	Emergency dept visit	$325.26	$344.81
Total Payment		**$546.51**	**$344.81**

Outpatient clinic visit with S & I Example

HCPCS Code	Short Descriptor	Sum of 2007 Payment (72240 Paid Separately)	Sum of 2008 Proposed Payment (72240 Packaged)

62284	Injection for myelogram (dependent service)	$0.00	$0.00
Q9947*	LOCM 200-249mg/ml iodine, 1ml (dependent service)	$64.24	$0.00
72240	Myelogram cervical S&I	$157.01	$0.00
99214	Outpatient Office Visit	$84.87	$84.87
Total Payment		**$306.12**	**$84.87**

Another Emergency Room with S & I Example

HCPCS Code	Short Descriptor	Sum of 2007 Payment (75671 Paid Separately)	Sum of 2008 Proposed Payment (75671 Packaged)
75671 (Q status indicator)	Angio carotid, cerebral bilateral S&I	$1295.05	$0.00
Q9947*	LOCM 200-249mg/ml iodine, 1ml (dependent service)	$64.24	$0.00
36100	Introduction of needle or intracatheter carotid or vertebral artery	$0.00	$0.00
99285	Emergency dept visit	$325.26	$344.81
Total Payment		**$1684.55**	**$344.81**

*** = indicates the proposed change of contrast material from a payable status to a non-payable status**

Under the CY 2007 final rule, CMS created a new status indicator of "Q" (special packaged codes) to represent special packaged codes that are only payable on a claim with no separately payable OPPS services reported. The examples below show that because there is a payable service (emergency room visit) on the claim the status indicator Q now becomes status indicator of N and payment is based on the emergency room visit. HCPCS 75671 is rarely reported as a stand alone service. For example, a patient is admitted to observation from the emergency room for chest pain (payable observation diagnosis CY 2007), dizziness, history of a stroke, TIA and prior DVT. Physician orders an EKG, labs, and a carotid angiography.

Observation Example -- Admitted from the Emergency Room

HCPCS Code	Short Descriptor	Sum of 2007 Payment	Sum of 2008 Proposed

			Payment
75671 (Q status indicator)	Angio carotid, cerebral bilateral S&I	$1295.05	$0.00
Q9947*	LOCM 200-249mg/ml iodine, 1ml (dependent service)	$64.24	$0.00
36100	Introduction of needle or intracatheter carotid or vertebral artery	$0.00	$0.00
G0378 (under criteria for separately paid observation care)	Hospital observation per hr (dependent service)	$442.81	$0.00
99285	Emergency dept visit	$325.26	$344.81
Total Payment		**$2127.36**	**$344.81**

Observation Example -- Direct Admit from Clinic

HCPCS Code	Short Descriptor	Sum of 2007 Payment	Sum of 2008 Proposed Payment
75671 (Q status indicator)	Angio carotid, cerebral bilateral S&I	$1295.05	$0.00
Q9947*	LOCM 200-249mg/ml iodine, 1ml (dependent service)	$64.24	$0.00
36100	Introduction of needle or intracatheter carotid or vertebral artery	$0.00	$0.00
G0378 (under criteria for separately paid observation care)	Hospital observation per hr (dependent service)	$442.81	$0.00
99215	Outpatient office visit	$106.33	$106.33
Total Payment		**$1908.43**	**$106.33**

We would like to reiterate our respectful disagreement with the packaging approach, we request CMS to revaluate the proposed changes for CY 2008 and delay finalization until further review and analysis can be completed.

XI. Proposed Hospital Coding and Payment for Visits

In the April 7, 2000, OPPS final rule (65 FR 18434), CMS instructed hospitals to report facility resources for clinic and emergency department visits using CPT E/M codes and to develop internal hospital guidelines to determine what level of visit to report for each

patient. CMS also stated that each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes. CMS has proposed for CY 2008 that in absence of national guidelines, it requires hospitals to comply with a nationally proposed set of principals. These proposed principals will allow hospitals to continue reporting facility E/M codes using their established internal guidelines for hospital clinic visits.

We commend the efforts of CMS for diligently working to a solution regarding national guidelines for clinic level visits. CMS has reviewed many different models, solicited many comments from various hospitals, AHA, AHIMA and experts in their field. We understand the difficulty placed on CMS to come up with a reproducible nationally standardize set of guidelines for use by all hospitals and specialties. We recommend that CMS should finalize the set of principals as written in the proposed CY 2008 rule.

We thank CMS for taking the time to review our comment concerning the CY 2008 proposed rule published August 2, 2007 in the Federal Register.

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Intacs CORNEAL IMPLANTS

AlphaCor™ ARTIFICIAL CORNEA

September 14, 2007

RECEIVED - CMS
2007 SEP 17 P 4:06

Rec 9-14-07
EB

Kerry N. Weems
Acting Administrator
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P

Dear Mr. Weems:

Addition Technology, Inc. ("ATI") would like to thank you for the opportunity to comment on Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System ("OPPS") and CY 2008 Payment Rates" (the "Proposed Rule") published in the *Federal Register* on August 2, 2007.[1] As requested, we have keyed our comments to the relevant issue identifiers in the Proposed Rule.

At the outset we wish to commend and thank the members of the hospital outpatient prospective payment system team with whom we have been working. Throughout this process we have felt that these individuals have given their time and attention to the problematic circumstances surrounding integrated keratoprosthesis (CPT Code 65770). We also would like to thank you for the proposed payment increase to $5,290.37 for performing this procedure. This payment rate will help mitigate the financial loss incurred by hospitals when they offer AlphaCor to their patients.

Unlike hospital outpatient departments, ambulatory surgical centers ("ASCs") are facing a drastic cut in payment for the procedure. Under the standard ASC methodology, for 2008, the proposed unadjusted payment rate is only $1605.93 for both the procedure and device because the cost of the device will be packaged into the payment rate for the procedure.

We are deeply concerned that CMS' proposal to reimburse ASC at a payment rate of $1,605.93 for performing an integrated keratoprosthesis will impair Medicare beneficiaries access to this last resort treatment in the ASC setting. Accordingly, we recommend that CMS designate integrated keratoprosthesis (CPT Code 65770) as a device intensive procedure to ensure that this procedure is appropriately paid in the ASC setting.

---

[1] 72 *Fed. Reg.* 42626 (Aug. 2, 2007).

ADDITION TECHNOLOGY, INC.
A VMG, LLC INVESTMENT COMPANY

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Main: 847-297-8419 - Fax: 847-297-8678

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OPPS: DEVICE-DEPENDENT APCS
ASC IMPACT

I. CMS SHOULD ENSURE THAT MEDICARE BENEFICIARIES CONTINUE TO HAVE ACCESS TO INTEGRATED KERATOPROSTHESIS

A. Integrated keratoprosthesis is a last resort treatment option for a limited patient population

AlphaCor™ was cleared by the FDA in 2002 and designed replace a scarred or diseased native cornea. It is the only technology available today that is a flexible, bio-integratable, one piece synthetic cornea made of poly-HEMA, with a 7.0 mm diameter. While the majority of Medicare beneficiaries are successfully treated with a standard corneal transplant procedure, keratoprosthesis implantation using AlphaCor provides a critical treatment option for those patients who are not candidates for a corneal transplant procedure. Keratoprosthesis is a last resort procedure for those patients with corneal opacity not suitable for standard penetrating keratoplasty with donor tissue, who have rejected donor tissue or where adjunctive measures required to prevent graft rejection are medically contraindicated. Left untreated, these Medicare beneficiaries likely will become blind.

B. Severe payment disparity in the ASC setting will exist in 2008

We are deeply concerned that access through ASCs will become essentially non-existent in 2008 if integrated keratoprosthesis is not treated as a device intensive procedure. In 2006, only approximately 80 procedures using AlphaCor were performed.[2] ASCs are an important site of service for this procedure. In 2006, approximately 75% of the integrated keratoprosthesis procedures performed in the United States were performed in the ASC. We fear that ASCs will find it financially impossible to continue to offer the procedure at this grossly inadequate payment rate resulting in fewer provider options for Medicare beneficiaries.

ASCs are facing a drastic cut in payment in 2008. In 2007, ASCs received two payments when they performed integrated keratoprosthesis: (1) an (unadjusted) ASC facility rate of approximately $995 for the procedure and (2) a payment for the cost of the device itself. The manufacturer cost of the AlphaCor device is $6,950 (excluding shipping costs). Under the standard ASC methodology, for 2008, the proposed unadjusted payment rate is only $1605.93 for both the procedure and device because the cost of the device will be packaged into the payment rate for the procedure. This reimbursement rate is clearly inadequate when it does not even cover the cost of the device, which is approximately $7,000. ASCs will no longer perform the procedure if the payment rate is insufficient to cover their costs resulting in limited patient access to integrated keratoprosthesis.

---

[2] This number includes all public and private payors, not just Medicare beneficiaries. The number of procedures performed remains constant each year. In 2005, only 78 procedures using AlphaCor were performed.

II. CMS SHOULD DESIGNATE CPT CODE 65770 AS A DEVICE-INTENSIVE PROCEDURE

We believe that CPT Code 65770 meets the criteria for a device-intensive procedure in the ASC setting. CMS created an exception to the standard ASC methodology for device-intensive procedures because it recognized that the standard ASC methodology (bundling the cost of the device with the procedure) may result in inadequate payment for device-intensive procedures.[3] Payment for device intensive procedures is the sum of: (1) the cost of the device portion (which is the OPPS unadjusted national rate multiplied by the device offset percentage calculated by CMS) and (2) the payment for the service portion (which is reduced by the applicable conversion factor). It is only the service portion of the OPPS rate that is reduced by 67%, not the device portion. Device-intensive procedure criteria are set forth in 42 CFR §416.171:

1. The procedure must be a device-dependent APC under OPPS. Device-dependent APC's are procedures that usually, but not always, require a device to be implanted or used to perform the procedure and

2. The APC must have a device cost of greater than 50% of the median cost of the APC. CMS calculates the device cost used by applying a device offset percentage (which it calculates based on claims data) to the median cost.

A. APC 0293 should be designated as a device-dependent APC

APC 0293 (Level V Anterior Segment Eye Procedures) meets the criteria for a device-dependent APC. This APC consists of only one procedure, integrated keratoprosthesis. Device-dependent APC's consist of procedures that usually, but not always, require a device to be implanted or used to perform the procedure. Integrated keratoprosthesis always requires the implantation of an artificial cornea. CMS recognized that the procedure requires a device to be implanted when it assigned that device edits to the CPT Code 65770:[4]

> Where there are device HCPCS codes for all possible devices that could be used to perform a procedure that always requires a device and the APC is designated a device-dependent APC, we have commonly instituted device edits that prevent payment of claims that do not include both the procedure and an acceptable device code. In that way, hospitals become aware of the proper coding requirements, and we can be confident that our procedure claims include charges for the necessary devices so we can establish appropriate payment rates for those procedures. . . .After carefully considering the comments received, we are adopting our proposal without modification to assign CPT code 65770 to APC 0293, with

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[3] 72 *Fed Reg* 42628, 42504 (Aug. 2, 2007).
[4] 71 *Fed Reg* 67960, 68053-54 (Nov. 24, 2006).

a median cost of $3,177.05 for CY 2007. We are also assigning a procedure-to-device edit for CPT code 65770 with APC 0293.

We believe that it is reasonable for CMS to designate APC 0293 as the device dependent APC. It is the only APC listed in the January 2007 device edit file that is not listed as a device-dependent APC in the Proposed Rule, except for two categories of APCs. The first category consists of APCs that CMS is proposing will be deleted from the list of device-dependent APCs due to migration of HCPCS codes to other APCs. The other category of APCs consists of a mix of procedures, some of which do not require devices to perform the procedure and do not have a device edit. These categories are distinguishable because they do not, or will no longer, meet the device-dependent APC criteria.

Based on the fact that APC 0293 consists entirely of one procedure, integrated keratoprosthesis, that always requires the use of a device to perform the procedure (as evidenced by the assignment of the device edit), the procedure satisfies the first prong of the device intensive procedure test.

B. The device costs of APC 0293 is likely greater than 50% of the median costs of the APC

We believe that the device offset for APC 0293 will likely be greater than 50% of the median costs of the APC. We used the prices the carriers have established in their fee schedules for the device code L8609 (artificial cornea) to develop an estimate for the device offset percentage. Based on our estimate, the device costs likely will represent more than 50% of the median costs of the APC.

	Estimated Median Cost Percentage
OPPS CY 2008 median cost for APC 0293[5]	$5,224.94
Manufacturer cost of the AlphaCor device	$6,950 (excluding shipping costs)
Carrier DMEPOS Schedule Fee for the device L8609 (artificial cornea)	Range of $4,900 to $6,530
Estimate Device Cost Percentage of APC 0293 (using the lowest carrier price)	**94% (based on the lowest carrier payment)**

Based on our estimate, we suspect that the median cost files for APC 0293 will indicate that the device offset percentage is greater than 50% and the second prong of device-intensive procedure

[5] We obtained the median cost from the median cost files for services payable under the Hospital OPPS in calendar year 2008. The data are based on claims for hospital outpatient services provided January 1, 2006 through December 31, 2006.

will also be met. We respectfully ask that CMS review the median cost files to determine whether the 50% threshold would be satisfied for APC 0293.

We believe that CPT Code 65770 meets the device intensive procedure criteria. Accordingly, we recommend that CMS designate integrated keratoprosthesis (CPT Code 65770) as a device intensive procedure to ensure that this procedure is appropriately paid in the ASC setting. We request that CMS assign APC 0293 to a device-dependent APC and assign payment indicator "H8".

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ATI would again like to thank CMS for the opportunity to submit formal comments on the Proposed Rule. We urge CMS to designate integrated keratoprosthesis as a device-intensive procedure to ensure that ASCs are adequately reimbursed for providing keratoprosthesis and that Medicare beneficiaries continue to have access to this innovative, last resort treatment option.

Sincerely,

William Flynn
President & CEO

Bayer HealthCare

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September 14, 2007

By Hand Delivery

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
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Washington, DC 20201

Re: CMS-1392-P: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Bayer Healthcare LLC ("Bayer") thanks the Centers for Medicare and Medicaid Services ("CMS") for its continued efforts to ensure that beneficiaries have access to high-quality drugs and biologicals under the Medicare program. We appreciate this opportunity to comment on the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rules (the "Proposed Rule").[1]

For more than 100 years, Bayer has produced high-quality drugs and biologicals that have helped patients lead healthier lives. Our specialty pharmaceutical company, Bayer HealthCare Pharmaceuticals, is a worldwide leader. Its research and business activities are focused on the following areas: diagnostic imaging, hematology/cardiology, oncology, primary care, specialized therapeutics and women's healthcare. Our company ranks among the top 10 specialty pharmaceutical companies worldwide and is differentiated by our focus on innovation and customer orientation.

Based on this experience, we present the following comments, in summary, for your consideration:

- *Specified Covered Outpatient Drugs.* Bayer is deeply concerned regarding CMS' determination of the payment rate for specified covered outpatient drugs ("SCODs"). The Social Security Act ("the Act") requires that the payment rate for each SCOD be individually calculated on a drug-by-drug basis. CMS' aggregate calculation of a payment rate at 105 percent of the drugs' Average Sales Price ("ASP") violates the plain language of the Act and threatens beneficiary access to SCODs. Bayer respectfully

[1] 72 Fed. Reg. 42,628 (Aug. 2, 2007).

requests that CMS maintain payment at 106 percent of ASP until it individually calculates the proper payment rate for each SCOD in a manner consistent with its statutory mandate.

- *Pharmacy Overhead Charges.* Bayer supports the Advisory Panel on Ambulatory Payment Classification Groups (the "APC Panel") recommendation that CMS establish three drug overhead categories for hospitals to report their pharmacy overhead charges associated with each drug provided in the hospital outpatient department. If pharmacy overhead charges are to be packaged, however, we recommend that they be packaged with the drug itself, rather than the drug administration service. We strongly disagree with the proposal to instruct hospitals to remove the pharmacy overhead charges from the charge for the drug and instead report such costs on an uncoded revenue line, as such reporting is unlikely to generate consistent, reliable and accurate data on pharmacy overhead costs from hospitals.

- *Packaged Services.* Bayer strongly believes that contrast agents should be reimbursed separately by CMS. Furthermore, Bayer respectfully requests that CMS proceed cautiously in its proposal to package "dependent" items and services other than contrast agents, such as image processing services and imaging supervision and interpretation services, into large ambulatory payment classifications representing the "independent" encounter. CMS should ensure that these packaged services and items are adequately reimbursed, thereby ensuring continued beneficiary access to these items and services.

- *Packaging Drugs and Biologicals.* Bayer respectfully requests that CMS eliminate the $60 threshold and reimburse all drugs and biologicals, including contrast agents, separately, as recommended by the APC Panel. Unpackaged payment is necessary to ensure that Medicare payment rules do not impede beneficiaries' access to vital treatments.

These comments are discussed in further detail below. We thank CMS in advance for its consideration of them.

I. OPPS: SPECIFIED COVERED OUTPATIENT DRUGS

We are disappointed with CMS' proposals regarding the payment for SCODs as well as the packaging of pharmacy overhead costs. Bayer continues to remain deeply concerned with the proposed reimbursement of SCODs at 105 percent of ASP. We question the legal basis of CMS' determination to reduce SCOD reimbursement.

Furthermore, based on our analysis of the relevant underlying Government Accountability Office ("GAO") and Medicare Payment Advisory Commission ("MedPAC") data, we fear that in some instances, this proposal will inadequately reimburse hospitals for drug acquisition costs and pharmacy overhead costs and, therefore, threaten beneficiary access to vital drugs. In addition, we question whether CMS' intention to package pharmacy overhead costs for drugs and biologicals into payment for the associated procedure represents a wise policy decision, given that such packaging does not directly account for the variety in the complexity and handling and storage requirements of different drugs used for the same encounter. Therefore, we respectfully request that CMS continue to reimburse SCODs at 106 percent of ASP and reconsider the packaging of pharmacy overhead costs.

A. Until CMS Can Perform an Individualized Determination of the Payment Rate for Each SCOD, CMS Should Maintain the Payment Rate at 106 Percent of ASP.

Section 1833(t)(14)(A) of the Act requires that payment for "a specified covered outpatient drug" be equal to the average acquisition cost for "the drug" for that year.[2] In other words, the Act contemplates an individualized reimbursement determination for each SCOD. However, the Proposed Rule reveals that CMS has not undertaken such an individualized determination, but rather, has estimated the "aggregate expenditures for all drugs and biologicals ... and calculated the equivalent average ASP-based payment rate."[3] We believe that CMS' aggregate methodology for calculating the ASP payment rate violates the plain language of the Act and threatens to render certain drugs unaffordable to hospital outpatient departments and unavailable to beneficiaries. Until CMS properly calculates the SCOD payment rates on a drug-by-drug basis, we urge CMS to maintain the status quo payment rate at 106 percent of ASP.

Congress required CMS to make an individualized determination with respect to each SCOD to ensure that hospitals would not avoid providing any of these vital drugs to beneficiaries based on a shortfall in federal reimbursement.[4] As GAO noted, "[C]ongressional concerns were raised that beneficiaries might lose access to some of these products if hospitals avoided providing them" because of inadequate reimbursement.[5] CMS' aggregate calculation of the ASP payment rate for

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[2] Emphasis added.
[3] 72 Fed. Reg. at 42,735.
[4] 42 U.S.C. § 1395*l*(t)(14)(A).
[5] U.S. Government Accountability Office, Comments on Proposed 2006 SCOD Rates (GAO-06-17R) at 4 (Oct. 31, 2005) (emphasis added).

SCODs may broadly reflect hospitals' average acquisition costs for all of the approximately 500 drugs and biologicals payable under the OPPS, but the methodology falls dangerously short of fulfilling Congress' intent to ensure beneficiary access to each of these complex and innovative therapies.

For example, a 2007 report by the Office of Inspector General ("OIG") concludes that in the third quarter of 2006, over 40 percent of intravenous immune globulin ("IVIG") sales to hospitals and physicians were at prices above Medicare payment amounts, clearly documenting the inadequacy of 106 percent of ASP reimbursement.[6] Although IVIG is just one example of the impact that inadequate reimbursement can have on beneficiary access, CMS fails to explain how a reduced payment amount—105 percent of ASP—will adequately compensate for IVIG acquisition costs plus the significant pharmacy overhead costs associated with the drug, when hospitals cannot even afford to acquire the drug at 106 percent of ASP. More importantly, CMS fails to explain how Medicare beneficiaries will continue to gain access to IVIG through hospital outpatient departments when such departments reluctantly cease administration of this drug due to less favorable reimbursement economics.

The potential reimbursement and beneficiary access problems extend beyond IVIG to other drugs. For this reason, in the 2007 Hospital OPPS Final Rule, CMS abandoned its proposal to reimburse SCODs at 105 percent of ASP.[7] CMS cited the "inherent complexity" of determining pharmacy overhead costs, its lack of understanding of the "full nature and magnitude" of such costs, and the concern that 105 percent of ASP would not adequately cover both acquisition and pharmacy overhead costs.[8] CMS has not demonstrated why 105 percent of ASP will adequately reimburse drug and overhead costs in 2008, when such costs are no less complex or better understood than in 2007. Indeed, given the lack of detailed data on hospital's pharmacy overhead costs, we fear that the 105 percent reimbursement rate will render certain SCODs unaffordable to hospital outpatient departments.

CMS' methodology of setting an aggregate ASP payment rate for the approximately 500 OPPS drugs assumes that, *on average*, any

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[6] Department of Health and Human Services, Office of Inspector General, Intravenous Immune Globulin: Medicare Payment and Availability (OEI-03-05-00404) at ii (Apr. 2007). The report notes that the percentage of hospitals acquiring IVIG below the Medicare payment amount was once as low as 23 percent. *Id.*

[7] 71 Fed. Reg. 67,960, 68,091 (Nov. 24, 2006).

[8] *Id.*

financial losses arising from the use of any particular SCOD will balance any overpayment with respect to a different drug. However, this may not be the case where hospitals utilize higher percentages of the more costly drugs, and lower percentages of the drugs with more favorable reimbursement economics. As a result of CMS' calculation of an aggregate ASP payment rate, such hospitals find themselves in a double bind—either they shift utilization towards the drugs with more favorable reimbursement, reducing or eliminating access to drugs with comparatively less favorable economics thus threatening beneficiary care, or they continue to acquire and administer drugs whose costs exceed reimbursement rates, threatening the financial viability of the hospital outpatient department.

The Congressional mandate of an individualized determination of SCOD reimbursement was intended to avoid these serious problems. By requiring reimbursement for "a" SCOD to be set equal to the average acquisition cost for "the drug," Congress sought to ensure that hospitals would make their pharmacy and medical decisions based on the best interests of the Medicare beneficiary, rather than the economics of the pharmaceutical marketplace. In other words, Congress sought to ensure that Medicare beneficiaries would have continued access to the full panoply of OPPS drugs and biologicals.

The courts have been clear in a series of cases that the plain language of a statute must be honored by a regulatory agency.[9] Regulatory agencies do not have the discretion to deviate from the plain language of a statute. By setting reimbursement for SCODs at 105 percent of ASP, we conclude that CMS will be violating the plain

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[9] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted). Indeed, a regulatory agency "has no power to correct flaws that it perceives in the statute it is empowered to administer. Its rulemaking power is limited to adopting regulations to carry into effect the will of Congress as expressed in the statute." *Board of Governors of Federal Reserve System v. Dimension Financial Corp.*, 474 U.S. 361, 374, 106 S.Ct. 681, 689 (1986) (footnote omitted). However, even putting this point to the side, we see no flaws, perceived or otherwise, with the plain language of the MMA provision. It is not a flawed policy to require, as Congress did, that costs be determined on a drug by drug basis. Indeed, this is the best means of ensuring appropriate payment.

language of the Act and subverting the Congressional scheme to ensure beneficiary access to medically necessary drugs.

Until data becomes available enabling CMS to perform an individualized, drug-by-drug determination of the payment rate for each of the SCODs, we respectfully request that CMS maintain the current payment rate at 106 percent. Although such a rate cannot ensure beneficiary access to each of the SCODs, the maintenance of the status quo will allow hospitals to refrain from making further reductions in items or services provided to beneficiaries, and avoid a site of service reimbursement differential between the hospital outpatient and physician office settings.

B. CMS Should Not Package Pharmacy Overhead Costs With the Associated Procedure.

Pharmacy overhead costs depend upon the unique characteristics of each drug, rather than the procedures in which the drugs are used. Accordingly, Bayer remains concerned that CMS intends to separate the pharmacy overhead costs from the costs of the drugs and biologicals for the purposes of packaging the pharmacy overhead costs with payment for the associated procedure. We believe that CMS should reexamine the APC Panel proposal to create three drug overhead categories that hospitals may use to report pharmacy overhead charges.

Pharmacy overhead costs encompass a wide variety of costs including the preparation, storage, transportation, dispensing, and disposal of drugs and biologicals, and may include such other costs as quality control and inventory management. These costs are drug-specific, rather than procedure-specific, and are primarily determined by the storage and handling instructions in the product labeling, rather than the specifics of any one procedure.

By linking pharmacy overhead costs with procedures rather than drugs, CMS erroneously assumes that different drugs with the same indication will have comparable pharmacy overhead costs. To the contrary, the drugs may require different storage conditions (refrigeration vs. room-temperature storage), handling (safety precautions, sterility, need for reconstitution or compounding), and disposal (depending upon toxicity or environmental concerns), and may have different shelf-lives or inventory turnover, requiring differential investments of pharmacy labor.

Packaging pharmacy overhead costs with the associated procedures is unlikely to capture adequately the important differences in handling and storage for drugs and biologicals used for the same

procedures. Therefore, we recommend that CMS reexamine the APC Panel's recommended plan to establish three drug overhead categories that reflect the different amount of resources a pharmacy must devote to the proper storage and handling for the drugs. As CMS noted in the Proposed Rule, other interested stakeholders have made similar proposals,[10] indicating broad public acceptance of the APC Panel's model, which speaks favorably to the merits of such a proposal.

In any event, we counsel against moving forward with the proposal to instruct hospitals to remove the pharmacy overhead charges from the charge for the drug and instead report such costs in a separate code. Bayer has considerable concerns regarding the reliability and accuracy of separately reportable hospital claims data for pharmacy overhead costs. We believe that the proposal fails to account for the divergent practices of hospital outpatient departments, which tend to disperse overhead costs across a wide range of hospital costs. Because there will not be any payment associated with such a separately reportable charge in CY 2008, there will be no incentive for hospitals to deviate from their historical practices of spreading costs. Even as an interim step, we fear that the proposal will gather unreliable data and that any actions taken based on such flawed information can only lead to unsound policy-making.

Although CMS is correct in noting that pharmacy overhead would remain unpackaged from OPPS payment for the procedure, we believe that such separate payment is necessary in order to avoid inadequately reimbursing hospitals for their pharmacy overhead costs, particularly when taken with CMS' proposal to reduce payment for SCODs to 105 percent of ASP. Hospitals must devote significant resources in order to ensure that drugs and biologicals are properly stored, handled, and dispensed in order to safeguard beneficiaries' health and safety. Because we believe that CMS' pharmacy overhead proposal will jeopardize hospitals' ability to perform these vital services for beneficiaries, we respectfully request that CMS reconsider its proposal.

II. OPPS: PACKAGED SERVICES

A. CMS Should Not Package Contrast Agents.

Bayer strongly disagrees with CMS' proposal to package contrast agents, including those above the proposed $60 threshold, with the services with which they are associated. As discussed below in Section III, Bayer believes that CMS should eliminate the $60 threshold and reimburse all drugs and biologicals separately. Please refer to

[10] 72 Fed. Reg. at 42,734.

Section III for our discussion of why drugs and biologicals, and contrast agents in particular, should not be packaged.

B. CMS Should Proceed Cautiously in its Proposal to Package "Dependent" Items and Services Other than Contrast Agents.

Bayer respectfully requests that CMS proceed with extreme caution in its proposal to package "dependent" items and services other than contrast agents into large ambulatory payment classification ("APC") groups for a particular encounter. We appreciate the conceptual simplicity of a prospective encounter-based system but remain concerned that the functional complexities of such a system, if not addressed properly, may negate the system's benefits. We hope, as does CMS, that the packaging of related healthcare items and services will encourage hospital efficiency and reduce unnecessary or wasteful expenditures; but, we fear that, absent appropriate reimbursement for the packaged services, packaging will inevitably result in the reduction of the quantity and quality of outpatient services provided to Medicare beneficiaries.

The integration of payment for "independent" procedures with their dependent items or services, such as image processing services and imaging supervision and interpretation services, likely will affect hospitals' behavior with respect to an encounter's independent and dependent components. For example, if reimbursement for the packaged items and services is inadequate, hospitals will face financial pressure to alter their use of, or devote less resources to, the dependent item or service. CMS subtly acknowledges this possibility by promising repeatedly to carefully monitor billing practices for signs of fraud or quality of care issues detrimentally affecting Medicare beneficiaries.[11]

CMS' proposed monitoring of billing practices, however, will not suitably address or alleviate the financial pressures faced by hospitals due to inadequate reimbursement, but merely detect those hospitals who respond inappropriately to those pressures. Moreover, such monitoring would be unnecessary if CMS were to establish an adequate packaged payment for the entire encounter, thereby eliminating the pressure placed on hospitals to either absorb financial losses for the encounter, or devote fewer resources to the dependent items and services. Therefore, we request that CMS take a very cautious and nuanced approach to determining payment for APCs to avoid any unintended consequences detrimental to hospitals' financial, or beneficiaries' physical, well-being.

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[11] *See id.* at 42,657, 42,659, 42,661, 42,664, 42,671, 42,673, and 42,677.

Bayer trusts that CMS will take a thoughtful, cautious approach to the packaging of dependent items and services other than contrast agents, and we write here to support CMS in such careful efforts. As CMS has come to understand in the Part A context, prospective encounter-based payment systems can successfully reduce hospital inefficiencies and promote high quality of care for beneficiaries. Payment systems that do not appropriately account for the nuances and variable costs of patient care, however, run the risk of incentivizing the reduction, elimination, or devotion of inadequate resources to the performance of the independent and dependent items and services. Thus, given the serious risks to patient care that may result from inadequate reimbursement of packaged services, Bayer strongly recommends that CMS carefully consider the packaged payments that will be implemented for CY 2008.

III. OPPS: PACKAGING DRUGS AND BIOLOGICALS

Bayer supports the recommendation of the APC Panel that the drug packaging threshold for all drugs and radiopharmaceuticals be eliminated, and that all such products be paid separately. We believe that the packaging of drugs results in less accurate payment and, we fear, pressures hospital outpatient departments to rely upon less effective treatments. We fear that a different approach would be inconsistent with the critical goal of ensuring a high quality of care and beneficiary access to necessary treatments. Therefore, we strongly maintain that CMS should separately reimburse all drugs and biologicals, including contrast agents.

Despite CMS' statement that packaging "could provide significant incentives for hospital efficiency in adopting the most cost-effective approaches to patient care, while providing hospitals with maximum flexibility in managing their resources,"[12] CMS later concedes that this "cost-effectiveness" and "flexibility" is likely to restrain drug treatment options for beneficiaries, to their detriment. Indeed, CMS has proposed to maintain separate payment for 5HT3 anti-emetic products precisely in order "to ensure that Medicare payment rules do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[13]

CMS' proposal to package drugs and biologicals, including contrast agents, likely will negatively impact beneficiaries' access to medically necessary treatments. For example, Bayer is particularly

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[12] *Id.* at 42,732.
[13] *Id.* at 42,733.

concerned that CMS' proposal will cause hospitals to inappropriately restrict the use of higher cost contrast agents that provide high resolution images in magnetic resonance imaging ("MRI") procedures.

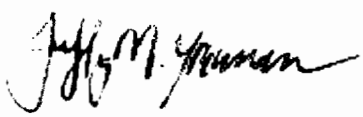
Bayer manufacturers the MRI contrast agent Magnevist® (gadopentetate dimeglumine), a gadolinium-based contrast agent used by physicians to distinguish normal and abnormal tissue in the brain and body, and to provide information about blood supply to organs and limbs, or the size and location of tumors. Because gadolinium-based agents allow physicians to image the body with greater clarity, providers rely upon gadolinium-based agents to improve their analysis of patients and plan a specific course of treatment for the patient. Were CMS to create a packaged payment for MRI imaging that fails to adequately cover the costs of gadolinium-based contrast agents, hospitals may forego the use of such medically indicated agents, to the detriment of vulnerable beneficiaries.

Although this example deals specifically with contrast agents, we believe that the incentives illustrated here provide insight into the potential impact of CMS' packaging proposal more generally, with respect to all drugs and biologicals utilized by hospital outpatient departments. We strongly believe that CMS should eliminate the $60 packaging threshold for drugs and biologicals, and conclude that all drugs and biologicals, including contrast agents, should remain unpackaged, thereby ensuring beneficiary access to the treatments they and their physicians decide are most appropriate.

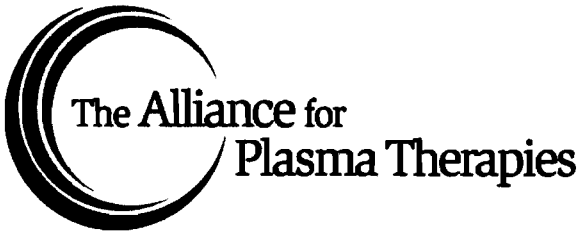
IV. CONCLUSION

We appreciate this opportunity to comment on the Proposed Rule, and we thank you for your consideration of the above comments. We would be happy to further discuss any or all of the aforementioned issues with CMS, and we look forward to continuing to work with CMS to improve the health of Medicare beneficiaries.

Sincerely,



Jeffrey M. Greenman
General Counsel and Secretary
Bayer HealthCare LLC and Bayer Pharmaceuticals Corporation



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September 14, 2007
Reference No.: FASC07056v1

Kerry Weems
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RE: CMS-1392-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Administrator Weems:

The Alliance for Plasma Therapies (the Alliance) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule detailing proposed payment policies in the Hospital Outpatient Prospective Payment System ("OPPS") for Calendar Year ("CY") 2008 ("Proposed Rule"). The Plasma Alliance was founded by concerned stakeholders within the immune globulin community who are troubled by access issues such as compromised patient care that is related to the diminution of the number of providers who are able to treat with IVIG given the changes in the reimbursement paradigm following the implementation of the Medicare Modernization Act.

The Alliance, a newly formed 501(c) (4) nonprofit organization, was created to provide a forum for patient organizations, healthcare providers and industry leaders to advocate with a unified, powerful voice for fair access to plasma therapies for patients who benefit from their lifesaving and life-enhancing effects. Our immediate goal is to ensure fair and adequate reimbursement for all brands of IVIG in all sites of care for all patients who benefit from IVIG therapy.

The Alliance's initial objectives include: to ensure fair and adequate reimbursement for all brands of IVIG in all sites of care: physician office, independent clinic, hospital and homecare; to be an IVIG access information resource for patient organizations, provider communities, Congress, federal and state agencies and others; to advocate to Congress and the U.S. Department of Health and Human Services for fair access to IVIG; and to support the creation of a Congressional Taskforce on IVIG access to work in conjunction with the Alliance on all legislative and public policy activities.

A. BACKGROUND:

Members of the IVIG community have consistently argued that the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) led to a reimbursement shortfall for IVIG therapies in the physician office setting. The MMA instituted the market-based manufacturer's average sales price ("ASP") for payment for most drugs under Medicare Part B, including IVIG when furnished by physicians and suppliers. By shifting reimbursement methodology in this site of service for IVIG from 95 percent of the average wholesale price ("AWP") to 85 percent of the AWP in 2004, and then finally to 106 percent of the ASP in 2005, the MMA significantly reduced reimbursement levels for IVIG in the physician office. When the ASP methodology went into effect in the physician office in 2005, the majority of physicians were unable to continue to offer IVIG therapies to their patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG. Many of these patients migrated to the hospital outpatient department to receive their IVIG infusions. Additionally, primary immune deficient patients who were covered in the home care setting were no longer able to receive their IVIG because the reimbursement formula went into effect for the home care setting under Part B and did not cover the administration or equipment needed in providing an IVIG Infusion.

In 2006, however, the problems that had only faced providers in the physician office and home care setting began to adversely affect providers in the hospital outpatient department setting. When CMS set the 2006 OPPS payment rates for specified covered outpatient drugs, the agency opted to use the ASP +6% methodology under section 1847A of the Social Security Act ("SSA"). CMS had such authority under the OPPS statute, which offers two mechanisms for determining OPPS payment rates for specified covered outpatient drugs for 2006 and beyond. Each of these mechanisms contains authority for CMS to adjust payments for these drugs, such as IVIG, as necessary.

Throughout this period of time and since then, patient organizations, providers and other members of the IVIG community have reported thousands of patients negatively impacted since the implementation of the MMA. Reports have also been submitted by many of these organizations in cooperation of investigations and studies by the government to determine the magnitude of the access problems, as well as the causes. Unfortunately, official government studies conducted and published by the U.S. Department of Health and Human Services Office of Internal General and the Assistant Secretary for Planning and Evaluation confirmed the access problems and the dramatic shift of 42% of IVIG Medicare beneficiaries from the physician site of care to the hospital outpatient setting. All of these patients have immune compromised systems and have had their care disrupted by change of location, change in brand of IVIG, reduction in IVIG dosage, or elimination of treatment altogether due to no site of care available. Such disruptions in IVIG access have been implicated as a factor in reports of up to nine Medicare beneficiaries' deaths. The nine fatalities include the following diagnosis in the following states: chronic lymphocytic leukemia, common variable immune deficiency, chronic inflammatory demylinating polyneuropathy, myasthenia gravis, myositis, and stiff person syndrome in California, Florida, Ohio, and Texas. It is important to note that this crisis has affected all patients who rely on IVIG as an effective treatment in all parts of the country.

Over the past years, members of the community have recommended to CMS administrative and legislative remedies to correct IVIG reimbursement problems. None of those recommendations have provided a long term solution to access issues. On the administration side, members of the community have worked hard to argue that IVIG is a biologic response modifier and should be reimbursed as such under the chemotherapy administration code and the response from CMS has always been to wait for a response from the American Medical Association's RUC to determine where IVIG should be classified.

B. COMMENTS ON 2008 PROPOSED RULE:

The Plasma Alliance is appreciative of the steps that CMS has taken to remedy the IVIG access problems that have been identified to date The Alliance is particularly encouraged that the agency decided to grant new brand specific "Q" codes effective July 1, 2007 to four liquid IVIG therapies and two other immune globulin therapies. We are also appreciative of the agency's decision to implement an additional payment for IVIG preadministration-related services and to continue this payment for reimbursement of Part B drugs. As is pointed out below, we hope that CMS will reconsider its proposal to reduce the preadministrative payment by almost 50% for drugs administered in the hospital outpatient setting.

The Plasma Alliance would like to specifically address several specific issues that were discussed in the 2008 OPPS proposed rule. These include:

1. Proposed 2008 OPPS reimbursement for IVIG

In the current OPPS proposed rule, CMS proposes to reduce the reimbursement for IVIG in the hospital outpatient setting from ASP +6% to ASP+5%.

> *Response: The Plasma Alliance believes that any reduction that affects IVIG at this time will lead to more disastrous results. We have seen a trend in hospitals shutting down their IVIG infusion clinics due to the cost of procuring IVIG being higher than the reimbursement from Medicare. If the ASP +6% is further reduced, hospitals, often the last site of care or the safety net for our nation, will eliminate access to this lifesaving therapy for their survival.*

2. Part B Drug Payment, ASP Issue:

The proposed rule also states that the ASP +6% formula be reduced to ASP + 5% for Part B reimbursement.

> *Response: Once again, a review the OIG report and the ASPE report demonstrates that a high percentage of hospitals and physician offices cannot provide IVIG because of the current reimbursement formula. Reducing the hospital to ASP +5% will put an increased burden on the hospitals that are currently treating over an increased number of patients relying on IVIG. The hospitals are the safety net of our country any further reductions will eliminate the last site of care for our patients.*
>
> *The Plasma Alliance requests the Administrator to retain reimbursement levels for Part B drugs at 2007 levels or ASP + 6%.*

3. Preadministration fee for Part B, OPPS:

In 2006 CMS put in place a preadministration fee for physicians and hospitals to locate product and schedule patients due to the major shift in patients from the physician's office to the hospital outpatient setting. In the 2008 proposed rules, CMS recommended to maintain the preadministration fee at the current level for the physician office only. For the hospitals, CMS has recommended to cut the reimbursement for the hospital outpatient setting by almost 50%.

Response: Hospitals are now absorbing the financial burden of finding product and scheduling a patient load.. Further complicating the situation that the most recent rule published by CMS proposes that CMS does not cover nosocomial infections that are acquired in the hospital. Since all patients that use IVIG are immune compromised either by having a primary immune deficiency where antibodies need to be replaced; autoimmune diseases; or immune mediated neuropathies these patients are all at a high risk of being exposed to an opportunistic infection in a hospital and in their compromised state it will be hard for them to fight the infection without any coverage for treatment.

In addition, hospitals continue to receive IVIG patients shifted from other sites of care. A reduction in the preadministration fee in hospital outpatient site of care could lead to the elimination of the last site of care for many patients leading to more fatalities.

In view of the above considerations, the Plasma Alliance would like to strongly encourage CMS to reconsider this proposed cut and to maintain the preadministration at the current level. In addition, the Alliance recommends that the preadministration fee be made permanent for both Part B and OPPS.

4. Payment for Administration Services:

In addition to the reimbursement for the product and preadministration-related services, CMS also reimburses providers for the costs of administering the infusion of IVIG. As you know, the Current Procedural Terminology ("CPT") codes of the American Medical Association ("AMA") are used for reporting medical services and procedures, including IVIG infusions. For example, the first hour of infusing IVIG is assigned to CPT code 90765, while the second hour of infusing IVIG is assigned to CPT code 90766. CMS assigns a value to these CPT codes, and for CY 2007, it designated $111.20 for CPT code 90765 and $24.25 for CPT code 90766. While the Alliance supports the agency's decision to increase the values of these codes for CY 2008 to $116.62 for CPT code 90765 and $25.71 for 90766, the Alliance believes these codes remain undervalued.

Response: IVIG is considered a complex biologic response modifier. The chemotherapy administration code includes other therapies such as monoclonal therapies and biologic response modifiers. The APC Panel has recommended that hospitals should be reimbursed on an hourly basis for infusions just like physician offices currently bill. Both the hospital and physician site of care are not being adequately reimbursed for the complexity of the administration of IVIG; therefore the Plasma Alliance recommends that CMS issue new administration codes for IVIG.

Further, the Alliance strongly urges CMS to issue two "G" codes in CY 2008 that will provide a more accurate reimbursement payment for the administration of an IVIG

infusion -- one to account for the first hour of IVIG infusion and one to be used for each additional hour of IVIG infusion. Under the HOPPS for CY 2008, CMS has proposed to assign values of $155.27 for the first hour and $52.93 for each additional hour to the two CPT codes for chemotherapy drug infusions. We support the APC Advisory Panel's past recommendations to make payments for each additional hour of an intravenous infusion beyond the first hour. This policy would follow the current policy in the physician office, and believe that all sites of care should be treated equally, especially given the length of time and the complexity of the administration of IVIG. The complexity of the infusion of IVIG is most similar to the infusion of chemotherapy drugs and in most hospital infusion suites, the nurses trained to administer IVIG are oncology infusion nurses. The adverse events that can occur with an IVIG infusion are many and can be severe such as: renal dysfunction; acute renal failure, osmotic nephrosis, thrombotic events, and death. We also believe that these codes and the assigned values should be used in the physician site of care.

C. CONCLUSION:

It is clear that patient access to IVIG has been negatively impacted since the implementation of the MMA. Reports and studies by the government and private entities have testified to the magnitude of the access problems, as well as to the causes. Importantly, the seminal studies of the OIG and ASPE have confirmed the access problems and the dramatic shift of 42% of IVIG Medicare beneficiaries from the physician site of care to the hospital outpatient setting.

Immuno-compromised patients have, unfortunately, experienced disruptions in care due to change of site of treatment, change in brand of IVIG, reduction in IVIG dosage, and/or elimination of treatment altogether due to no site of care being available. As the safety net for the nation's most vulnerable patients, the Plasma Alliance believe that Medicare should set the standard for compassionate care. The Plasma Alliance believes that compassionate care would include, at a minimum, that all patients where IVIG is an effective treatment should receive the most appropriate therapy in the most appropriate site of care.

The Plasma Alliance believes that CMS has the opportunity and the obligation to fix the IVIG access problems that have been clearly identified. We think that the adoption of the reimbursement remedies identified in this letter may help to solve many, if not most, of the access problems. The Alliance stands ready to discuss all or any of our recommendations with CMS. If you have any questions, please do not hesitate to contact me at 202-331-2194 or 202-329-8643.

Respectfully submitted,

Michelle B. Vogel
Director

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September 14, 2007

Herb Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1392-P: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Mr. Kuhn:

Talecris Biotherapeutics ("Talecris") submits the following comments in response to the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates (the "Proposed Rule").[1] We are committed to working openly with the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") in its development of payment policies that directly shape the provision of health care to Medicare beneficiaries.

Talecris is a company proud to have inherited a legacy of more than 60 years of providing lifesaving and life-enhancing plasma-derived therapeutic proteins. We are perhaps best known for our intravenous immune globulin ("IVIG") product, Gamunex® (Immune Globulin Intravenous (Human), 10% Caprylate/Chromatography Purified). We aim to be the recognized global leader in developing and delivering IVIG and other premium protein therapies.

In summary, Talecris presents the following comments for consideration:

- *IVIG Preadministration-Related Services.* We appreciate CMS' continued efforts to ensure patient access to IVIG. We urge the Agency to continue to monitor the adequacy of reimbursement for IVIG products.

- *Payment Rate Reduction.* We are particularly concerned with the Agency's proposal to reimburse separately payable drugs and biologics at the reduced rate of 105 percent of ASP. Such a proposal is of questionable legality and raises the potential for significant unintended beneficiary access issues.

- *Pharmacy Overhead Charges.* We read with concern CMS' proposal to instruct hospitals to remove the pharmacy overhead charges from the charge of the separately payable drug and to instead report such charges as a separate line item. Talecris questions CMS' proposed approach as we believe it will almost certainly lead to an inaccurate assessment of median

[1] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, Proposed Rule, 72 Fed. Reg. 42,628 (Jul. 12, 2007).

pharmacy overhead costs. We urge CMS to give serious consideration to the APC Panel recommendation that CMS establish three drug overhead categories for hospitals to report their pharmacy overhead charges associated with each drug provided in the hospital outpatient department. If, however, CMS must package pharmacy overhead charges, we encourage the Agency to package these charges with the drug itself, rather than the drug administration service.

- *OPPS: Blood Clotting Factors:* We disagree with CMS' proposal to reduce payment for blood clotting factors to 105 percent of ASP. However, we appreciate CMS' proposal to continue payment for the blood clotting factor furnishing fee. Such a proposal recognizes the importance of adequate Medicare reimbursement to preserve beneficiary access.

We thank CMS in advance for its consideration of our comments on these issues, which are discussed in detail below.

I. IVIG Pre-administration Related Services

As an IVIG manufacturer, Talecris read with interest the Agency's proposal to extend the add-on payment for the pre-administration-related services, per infusion encounter of IVIG through the assignment of HCPCS code G0032 to the new clinical APC 04030.[2] We thank the Agency for its continued attention to access-related IVIG issues. Moreover, we commend CMS for its recent decision to create product-specific codes for liquid IVIG products, effective July 1, 2007.[3] We believe the decision to issue separate codes will substantially alleviate beneficiary access to IVIG, and we encourage CMS to act swiftly to create permanent J-codes for IVIG products as part of CMS' commitment towards ensuring reliable access to this often life-saving therapy. Again, Talecris appreciates CMS' continued consideration of reimbursement and access-related IVIG issues. We look forward to continuing to work with the Agency on these important issues.

II. OPPS: Specified Covered Outpatient Drugs

Based on our review of the Proposed Rule, we offer comments on the following proposals: payment rate reduction for specified covered outpatient drugs ("SCODs"), pharmacy overhead fee, and blood clotting factors.

A. Payment Rate Reduction

Talecris is particularly concerned with the Agency's proposal to reduce the bundled payment amount for separately payable drugs and biologics for CY 2008 to 105 percent of ASP.[4] Last year, CMS made a similar proposal, which it wisely abandoned in the CY 2007 OPPS final rule, citing the "inherent complexity" of determining pharmacy overhead costs, its lack of understanding of the "full nature and magnitude" of such costs, and the concern that 105 percent of ASP would not adequately cover both acquisition and pharmacy overhead

[2] *Id.*
[3] Centers for Medicare and Medicaid Services, 2007 ASP Data, *available at* http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp (last visited August 20, 2007).
[4] 72 Fed. Reg. at 42,736.

[redacted]

costs.[5] But pharmacy overhead costs are no less complex or better understood than they were just one year ago. Accordingly, we are not persuaded that CMS has demonstrated why 105 percent of ASP will adequately reimburse drug and overhead costs in 2008 and fear that the 105 percent reimbursement rate will render certain SCODs unaffordable to hospital outpatient departments. Moreover, as discussed below, we believe such a reduction is of questionable legality and may result in unintended beneficiary access issues.

1. CMS' Proposal Is Of Questionable Legality.

Section 1833(t)(14)(A)(iii) of the Social Security Act (the "Act") requires that payment for SCODs be equal to the average acquisition cost of the drug for that year, as determined by the Secretary, subject to any adjustment for overhead costs.[6] Talecris is concerned that the Agency misconstrues section 1833(t)(14) of the Act because the Act does not contemplate the calculation of ambulatory payment classification ("APC") payment rates on a composite basis, rather on an individualized reimbursement determination on a per drug or biological basis.

We find the Agency's application of section 1833(t)(14)(A)(iii) of the Act to be inconsistent with a plain reading of the statute. Section 1833(t)(14) refers to the payment for "a specified covered outpatient drug" covered as part of a hospital outpatient department service, and defines the amount of payment as "the average acquisition cost for the drug."[7] With references to "a...drug" and "the drug" in the singular form, it is apparent to us that the plain language of the Act dictates that CMS determine drug APC payment rates on an individualized basis.

In a series of cases dating back more than 20 years, the courts have been clear that regulatory agencies lack the discretion to deviate from the plain language of a statute.[8] Congress could have required CMS to take into account the average price at which hospitals acquire all drugs. However, there is no evidence that Congress intended that CMS determine drug APC payments rates on anything other than a drug-by-drug basis. Accordingly, we believe CMS may not lawfully determine drug payments on a composite basis and therefore, we urge CMS to reconsider this proposal.

[5] 71 Fed. Reg. 67,960, 68,091 (Nov. 24, 2006).
[6] 72 Fed. Reg. at 42,734.
[7] Social Security Act § 1833(t)(14)(A)(iii) (emphasis added).
[8] "[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161, 120 S.Ct. 1291, 1315 (2000) (internal quotations and citations omitted). Accordingly, a regulatory agency "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 2781 (1984) (footnote omitted). Indeed, a regulatory agency "has no power to correct flaws that it perceives in the statute it is empowered to administer. Its rulemaking power is limited to adopting regulations to carry into effect the will of Congress as expressed in the statute." *Board of Governors of Federal Reserve System v. Dimension Financial Corp.*, 474 U.S. 361, 374, 106 S.Ct. 681, 689 (1986) (footnote omitted). However, even putting this point to the side, it is not a flawed policy to require, as Congress did, that costs be determined on a drug by drug basis. Indeed, this is the best means of ensuring appropriate payment.

[redacted]

2. Reduction In Reimbursement May Lead To Unintended Beneficiary Access Issues.

Recent IVIG access issues, in our experience, demonstrate the negative impact that inadequate Medicare reimbursement can have on beneficiary access. We fear that CMS' proposal to reduce the bundled payment amount for separately payable drugs and biologics to 105 percent of ASP may have significant, albeit unintended, beneficiary access issues.

Inadequate reimbursement for IVIG products has led to significant beneficiary access issues. Pursuant to the Medicare Modernization Act ("MMA"),[9] the ASP payment system first became the basis of Medicare reimbursement for services in physicians' offices in January 2005, and then in hospital outpatient settings in 2006. Reports of beneficiary IVIG access problems first surfaced in physicians' offices in 2005, and then in hospital outpatient settings in 2006 with the change in Medicare reimbursement levels. Medicare beneficiaries were shifted to different sites of service as a direct result of inadequate Medicare reimbursement rates.[10]

Various federal agencies have issued reports regarding the effects of inadequate reimbursement of IVIG products. The Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") concluded that "certain ASP-related issues" and the gaps between provider acquisition costs of IVIG and Medicare payment amounts caused physicians to shift patients to other sites of service.[11] The OIG's report found that for the 3Q 2006, 44 percent of distributors and 41.4 percent of physicians were unable to purchase IVIG at prices at or below the Medicare payment rate.[12] With nearly half of the distributors and physicians unable to purchase IVIG at or below Medicare payment rates, inadequate Medicare reimbursement was a significant cause of patient access issues.

The Assistant Secretary of Planning and Evaluation ("ASPE") also issued a report documenting IVIG access issues.[13] ASPE's report highlights several reports from physicians and hospitals alike reporting difficulties in obtaining IVIG at prices at or below the Medicare reimbursement amount.[14] ASPE's report confirms that changes in Medicare reimbursement directly impacts the provisions of IVIG therapy.[15]

It is clear from these reports that inadequate Medicare reimbursement has been the primary cause of IVIG beneficiary access issues. Because beneficiary access to IVIG has suffered in the past due to inadequate Medicare reimbursement levels, we fear a reduction to 105 percent of ASP will compound existing beneficiary access issues. While we believe the recent CMS decision to issue separate product-specific IVIG codes will significantly alleviate IVIG access issues, we fear that a further reduction in reimbursement negates any positive gains from such coding changes, at least in the hospital outpatient department setting.

[9] H.R. Res. 1, 106th Cong., 117 Stat. 2066 (2003) (enacted).
[10] Department of Health and Human Services, Office of Inspector General, *Intravenous Immune Globulin: Medicare Payment and Availability* (the "OIG report"), 15 (2007).
[11] *Id.*
[12] *Id.* at 9.
[13] Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous* (2007).
[14] *Id.* at 4-11.
[15] *Id.* at x.

[redacted]

We strongly caution CMS against reducing the Medicare payment to 105 percent of ASP. CMS' proposal is based upon questionable methodology, that uses ASP as a proxy for hospital acquisition costs and that we believe is contrary to the intent of the Act. Furthermore, we fear that not only will such a payment reduction negatively affect IVIG patients, but potentially a wide spectrum of Medicare beneficiaries. Accordingly, we urge CMS to reconsider its proposal to reduce the payment amount for separately payable drugs and biologics to 105 percent of ASP and instead maintain payment at 106 percent of ASP until individualized payments may be calculated.

B. Pharmacy Overhead Charges

Talecris read with concern CMS' proposal to instruct hospitals to remove the pharmacy overhead charges from the charge for the drug or biological and instead report such costs in an uncoded revenue code line.[16] First and foremost, we object to CMS not making separate payment for these charges. While we appreciate CMS' continued efforts to adequately reimburse for pharmacy overhead costs, we doubt the reliability and accuracy of separately reportable hospital claims data for pharmacy overhead costs. Alternatively, we recommend that CMS reconsider the Advisory Panel on APC Groups (the "APC Panel") recommendation to create three drug overhead categories that hospitals may use to report pharmacy overhead charges. In any event, if the Agency must package, we oppose the packaging of pharmacy overhead costs with a drug administration service and encourage CMS, if it must, to package these costs with the drug itself.

As noted in the Medicare Payment Advisory Committee ("MedPAC") report in 2005, hospital pharmacy handling fees are not insignificant and often account for 24 to 25 percent of a hospital pharmacy's direct costs.[17] These fees cover the costs associated with management of the pharmacy itself, including record keeping, personnel, and training. Pharmacy overhead fees ensure that adequate regulatory compliance, safety and quality measures are in place. The fees account for the supplies and equipment that are critical to drug safety, including maintaining drugs and their components in appropriate conditions. In addition, pharmacy handling fees must adequately reimburse for various components of preparation, which include reviewing orders, checking doses, mixing, compounding, or reconstituting the drug for administration. The costs of drug waste and supplies must also be covered by these fees. In addition to all of these costs, hospitals rely on pharmacy handling fees to cover costs for the labor, space, and additional expenses related to the general operation of the department.

While we appreciate CMS' interest in expanding packaging under the OPPS, we believe that the proposal inadequately reimburses hospital outpatient departments for pharmacy overhead costs. We fear that this particular proposal could lead hospital pharmacies to limit their expenditures across a host of pharmacy functions, including reducing the number of pharmacists and pharmacy technicians. As a result, beneficiary safety and quality measures could easily be compromised. For these reasons, we object to the packaging of pharmacy overhead costs and urge CMS to make separate payment for these charges.

If, however, CMS must package pharmacy overhead costs, we encourage it to withdraw its proposal and reconsider the alternatives. We have concerns about the merits of

[16] 72 Fed. Reg. at 42,734.
[17] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Issues in a Modernized Medicare Program* ("MedPAC Report"), 140 (June 2005).

[redacted]

the pharmacy overhead proposal. CMS' proposed methodology does not account for differences in hospital outpatient departments that disperse overhead costs over a wide range of overall costs to the hospital. Because hospital outpatient department costs are placed into different departments by different hospitals, a single cost to charge ratio as applied to different costs is problematic. One of the fundamental problems with CMS' proposal is that hospitals simply do not have precise information about the magnitude of pharmacy overhead costs, especially on a product specific basis.[18] In the hospital inpatient context, costs are difficult to assign to line numbers, particularly in cost centers where costs are shared.[19] Inaccurate reporting of costs can lead to distortment and severe misalignments in developing cost-to-charge ratios for hospital inpatient departments.[20] We fear that CMS' proposal to have hospital pharmacies report the costs on a separate line item presents similar difficulties.

We also have significant doubts as to the reliability of CMS' proposed methodology to give hospital pharmacies the discretion to report the overhead cost on a per drug or per episode basis.[21] Because the costs would be indistinguishable on a per drug or per episode basis, CMS' proposed methodology would inevitably lead to an overall inaccurate assessment of the median pharmacy overhead cost for a particular drug or biological. This proposal improperly assumes that packaging pharmacy overhead costs with the associated procedure will appropriately cover the overhead costs for those particular drugs and biologics. Contrary to CMS' proposal, the handling and storage costs for drugs and biologics differ on a per drug or biological basis, and simply cannot be appropriately calculated on a packaged basis with the underlying procedure.

The APC Panel recently noted the importance of pharmacy overhead fees and recommended a detailed three phase plan to address hospital pharmacy overhead charges.[22] We find merit in aspects of the APC Panel's recommendations for various phases of implementation, particularly in calling for CMS to create three drug overhead categories that hospitals may use to report pharmacy overhead charges. The APC Panel's proposal includes a number of strengths. Chief among them is the involvement of stakeholders. Because of the potential impact that it may have on beneficiary access, we believe that the value of stakeholder input at various phases of implementation is critical. We thank the Agency for its efforts to date to seek stakeholder input on this aspect of Medicare payment policy. We invite CMS to continue to keep stakeholders engaged as a means of preventing unintended consequences. It is important for CMS to consider data from a variety of sources, including the APC Panel, the Government Accountability Office and MedPAC.

[18] *Id.* (internal citation omitted).
[19] "Often charges are relatively easy to assign to appropriate line numbers but costs are not, particularly in closely related cost centers such as Operating Room, Anesthesia and Recovery Room. Reported costs may not be accurate in such areas if supervisory or other staff is shared, or if the allocation statistics used to accumulate general service costs are not sufficiently detailed to distinguish between the related departments. This can distort the numerator values (cost) in the cost-to-charge ratio. Severe misalignments can be identified through review of extreme values in hospitals' CCRs and the use of careful editing algorithms. Less severe misalignments, however, can only be identified and corrected through expanded cost report audits." RTI International, *A Study of Charge Compression in Calculating DRG Relative Weights Report* prepared for the Centers for Medicare and Medicaid Services, 23 (January 2007).
[20] *Id.*
[21] 72 Fed. Reg. at 42,734.
[22] *Id.*

[redacted]

We are particularly disappointed that CMS failed to more thoroughly consider MedPAC's recommendations.[23] MedPAC's June 2005 report provides a detailed analysis of this issue, contemplating three possible structures for the adequate payment of hospital pharmacy costs.[24] It outlines payment based on a markup on acquisition costs or a handling fee per administration, and consistent with CMS' expressed interest in bundling, it includes a discussion of payment based on larger payment bundles.[25] We caution, however, that as MedPAC points out, there are significant concerns that broad bundles "could adversely affect patient care" depending on how they are crafted.[26]

Pharmacy overhead fees are important to the appropriate operation of hospital pharmacies and help ensure the safe use of drug products. CMS' proposal would inadequately reimburse hospital pharmacies, compromising the integrity of the products from such pharmacies. Accordingly, Talecris urges CMS to give serious consideration to the APC Panel recommendation that CMS establish three drug overhead categories for hospitals to report their pharmacy overhead charges associated with each drug provided in the hospital outpatient department. But, if CMS must package pharmacy overhead charges, we encourage the Agency to package these charges with the drug itself, rather than the drug administration service. We are deeply troubled by the proposal to instruct hospitals to remove the pharmacy overhead charges from the drug charge and instead report such costs on an uncoded revenue line. Talecris fears that such reporting is unlikely to generate consistent, reliable and accurate data on pharmacy overhead costs from hospitals.

C. OPPS: Blood Clotting Factors

Based on our review of the Proposed Rule, we offer comments on the following proposals relating to blood clotting factors: payment for blood clotting factors and payment for the blood clotting factor furnishing fee.

1. Payment for Blood Clotting Factors

We strongly disagree with CMS' proposal to pay for blood clotting factors at 105 percent of ASP.[27] Above, we outline how CMS's aggregate calculation of a payment rate of 105 percent of the drugs' ASP violates the plain language of the Act and point out how the methodology underlying the proposed reduction is contrary to CMS' statutory mandate. In addition, however, we fear that such a reduction in the payment for blood clotting factor will threaten access even more for a particularly vulnerable group of Medicare beneficiaries who use these products. Based on our experience with IVIG products, we appreciate how reimbursement changes can deeply impact patient access to critical products. We fear a decrease in payment for blood clotting factors can lead to serious beneficiary access issues. Accordingly, we disagree with this proposal and urge CMS to maintain payment for blood clotting factor at 106 percent of ASP in CY 2008.

[23] *Id.*
[24] MedPAC Report, *supra* n.17 at 142.
[25] *Id.*
[26] *Id.*
[27] 72 Fed. Reg. at 42,736.

2. Payment for Furnishing Fee

Additionally, Talecris supports the payment of adequate blood clotting factor furnishing fees to physicians. As a result, we read with interest CMS' proposal to cease discussion of the furnishing fee update for blood clotting factors in the annual rulemaking process, and instead, communicate the blood clotting furnishing fee in CMS program instructions.[28] As we stated in our reply comments to the CY 2008 Medicare Physician Fee Schedule Proposed Rule,[29] we agree with CMS' proposal to issue communications regarding the furnishing fee updates in program instructions because the furnishing fee update process is statutorily determined and is based on an index that is not affected by administrative discretion or public comment.

III. CONCLUSION

On behalf of Medicare beneficiaries, we thank CMS for its ongoing work to ensure beneficiary access to critical, life-saving drug therapies. Please let us know how we can be of further assistance to the Agency in developing the final rule.

Sincerely,

Bruce Bunyan
Vice President
Corporate Communications and Public Policy

[28] *Id.*
[29] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, Proposed Rule, 72 Fed. Reg. 38,122 (Jul. 12, 2007).

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Because health matters

Hugh M. O'NEILL
Vice President

September 14, 2007

BY ELECTRONIC SUBMISSION

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Washington, D.C. 20201

Re: CMS-1392-P - Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Acting Administrator Weems:

Sanofi-aventis appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient and ambulatory surgery prospective payment systems, published in the Federal Register on August 2, 2007 (the Proposed Rule).1/ As a pharmaceutical company backed by world class research and development, we are developing innovative therapies to help Medicare beneficiaries lead longer, healthier, and more productive lives. We are pursuing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

Sanofi-aventis is committed to the fight against disease throughout the world. In the new millennium, we have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and

1/ 72 Fed. Reg. 42628 (Aug. 2, 2007).

launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs.

We applaud CMS' efforts to improve the quality of care in the hospital and ambulatory surgery settings and support the goals of developing and implementing performance measurement and reporting by hospitals and ambulatory surgery centers. As a company dedicated to bringing advanced therapies to patients, we believe that patients should have access to high quality care and offer several comments relating to the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). Many of the proposed measures affect therapeutic areas in which sanofi-aventis has therapies that can and do improve the lives of beneficiaries. As such, we have engaged with CMS and the quality measure developing and endorsing organizations to ensure measures are appropriate to ensure high quality care for Medicare beneficiaries. In particular, we urge CMS to adopt an agenda that provides for periodic revision of measures to ensure their continued validity and also includes the development of measures that address urgent medical needs among the Medicare population. We offer specific comments on the proposed measures and some considerations for additional measures in our comments below.

I. CMS Should Include the Proposed Acute Myocardial Infarction (AMI) and Diabetes Measures as Part of the Initial Measure Set for HOP QDRP [QUALITY DATA]

Sanofi-aventis applauds CMS for its efforts to improve the quality of care in the hospital outpatient department setting. In particular, we are pleased that CMS is proposing to include five AMI measures and a diabetes measure among the initial ten measures for reporting in 2008.2/ However, Sanofi-aventis encourages CMS to consider updating both the proposed AMI and the diabetes measures to reflect current scientific literature and treatment guidelines.

A. CMS Should Revise the Proposed AMI Measures

We agree with CMS that it is appropriate to include AMI measures in the initial HOP QDRP measure set, but we urge CMS to modify the AMI measures. In particular, the measures should require the administration of antiplatelet therapy (clopidogrel, aspirin) for patients with coronary artery diseases, as endorsed by the National Quality Forum (NQF) and recommended by the American College of Cardiology and American Heart Association Guidelines for Unstable Angina and

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2/ *Id.* at 42800.

Non-ST Elevation Myocardial Infarction.3/ Further, CMS should communicate its desire to update this measure, among others, to the measure developing and endorsing organizations as part of its measure development and update agenda for 2008. In the future, sanofi-aventis encourages CMS to consider adopting a system whereby participants in heart registries are deemed to have submitted and met necessary baselines for the AMI measures.

B. CMS Should Revise the Hemoglobin A1c Control Standard

We also concur with CMS's proposal to include a diabetes measure for 2008 HOP DQRP reporting. CMS should consider, however, revising the proposed Hemoglobin A1c control standard for patients with Type I or Type II diabetes mellitus4/ to be consistent with clinical guidelines established by the American Diabetes Association (ADA). These guidelines, supported by a broad collection of public health experts and medical societies, recommend lowering A1c to less than seven percent for people with diabetes in order to reduce the microvascular and neuropathic complications of diabetes.5/ PQRI measure #1 only requires documentation of A1c more than nine percent.6/ In the Proposed Rule, CMS indicates that the Hemoglobin A1c >9.0 percent measure is "an intermediate outcome measure that has not been risk-adjusted," and proceeds to describe its rationale for selecting the diabetes outcome measure.7/ Sanofi-aventis believes that the measure specifications should be modified to emphasize the current clinical guidelines, and we urge CMS to include revisions to this measure as part of its quality agenda for 2008 and beyond.

We acknowledge that, in the absence of an appropriate risk-adjustment, the nine percent measure is useful as an interim measure, but we believe that the measure could be better understood by physicians, consumers, and payers if it were rewritten as a positive goal to be achieved. In other words, rather than setting a target representing poor control (>9.0 percent), it might be easier for physicians, patients, and payers to monitor quality if the measure is rewritten to reflect good control (<7.0 percent). The National Committee for Quality Assurance (NCQA) Diabetes Physician Recognition program, for example, has diabetes recognition measures that set goals for the percentage of patients with good control (A1c <7.0

3/ NQF, National Voluntary Consensus Standards for Ambulatory Care: An Initial Physician-Focused Performance Measure Set at 10 (May 2006), available at http://www.qualityforum.org/; J. Anderson *et al.*, ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non–ST-Elevation Myocardial Infarction, J. Am. Coll. Cardiol. Vol. 50, No. 7, 45 (Aug. 14, 2007), available at http://content.onlinejacc.org/cgi/reprint/50/7/e1.

4/ 72 Fed. Reg. at 42800.

5/ CMS, 2007 Physician Quality Reporting Initiative Specifications Document at 2 (June 18, 2007), available at http://www.cms.hhs.gov/apps/ama/license.asp?file=/PQRI/downloads/Measure_Specifications_061807.pdf

6/ ADA, *Standards of Medical Care in Diabetes 2006*, Diabetes Care, 29:1 (Jan. 2006).

7/ 72 Fed. Reg. at 42800-01.

percent) and those with poor control (A1c >9.0 percent).8/ We believe acceptance of the 7.0 percent threshold by NCQA and its inclusion in the Healthcare Effectiveness Data and Information Set (HEDIS) suggests the measure should be considered for endorsement by NQF or AQA.

II. CMS Also Should Include Measures on Venous Thromboembolism and Care Coordination in the 2008 Measure Set [QUALITY DATA]

In addition to adopting the proposed AMI and A1c measures as part of the initial measure set for reporting in 2008, sanofi-aventis urges CMS to consider including measures on venous thromboembolism and care coordination as part of the measure set.

A. CMS Should Consider Additional Medical Prophylaxis Safety Measures to Improve Patient Care in the Hospital Outpatient Setting

We urge CMS to include two key measurements from the Surgical Care Improvement Project (SCIP) to any quality measures applied to the hospital outpatient department setting: venous thromboembolism (VTE) prophylaxis ordered for a surgery patient (SCIP-VTE 1) and VTE prophylaxis within 24 hours pre/post surgery (SCIP-VTE 2). These are measures CMS is proposing to add to the IPPS RHQDAPU for 20089/, and we believe they would be appropriate for the HOP QDRP as well. VTE occurs after approximately 25 percent of all major surgical procedures performed without prophylaxis. More than 50 percent of major orthopedic procedures are complicated by VTE if prophylactic treatment is not administered. However, in spite of the well-researched and established efficacy of preventive measures, studies show that VTE prophylaxis is often underused or used inappropriately. Incorporating the SCIP-VTE 1 and SCIP-VTE 2 into the HOPQDRP will help ensure that Medicare beneficiaries who undergo surgery on an outpatient basis receive appropriate quality care.

Sanofi-aventis also urges CMS to take the lead in calling for the development of a new VTE measure for prophylaxis of medical patients at risk for VTE. This is consistent with NQF-endorsed safe practices, which include:

- The evaluation of each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.

8/ NCQA and ADA, Recognizing Physicians for Excellence in Diabetes Care, 3, available at http://web.ncqa.org/LinkClick.aspx?fileticket=JXm2ViUPgog%3d&tabid=139&mid=860&forcedownload=true.

9/ 71 Fed. Reg. at 49672.

- The use of dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.10/

For patients who are seen in the outpatient setting and are at risk of developing VTE, evaluation and appropriate prophylactic treatment can reduce the risk of this life-threatening and often fatal condition. Sanofi-aventis believes CMS should expand the measures to include measures for prophylactic treatment of surgical and medical outpatients at risk for VTE.

B. CMS Should Take the Lead in Encouraging the Development of Measures for Coordination of Care

In addition to including quality measures regarding VTE, we encourage CMS to work with measure developing organizations and stakeholders, including groups such as the National Transitions of Care Coalition (NTOCC), to continue to include measures relating to care coordination in all of the quality reporting programs, including the HOP QDRP. The NTOCC is a coalition supported by sanofi-aventis that is dedicated to further care coordination via the development of appropriate tools, metrics, and policies.11/ Patients frequently are transferred between care settings, such as between primary care and specialty physicians, different departments in the hospital, or multiple facilities. During these transitions, it can be difficult to ensure sufficient communication between providers or across care settings in order provide continuity of care to a patient and ease the burden borne by patients and their families with regard to follow-up care. CMS is proposing to include measures that facilitate coordination among treating physicians in the HOP QDRP, as it does in PQRI (for example, Osteoporosis: Communication with the Physician Managing Ongoing Care Post Fracture).12/ We applaud CMS for adopting these reporting requirements and encourage CMS to work with the measure developing and endorsing organizations and groups such as the NTOCC, to continue to develop measures and requirements that further care coordination.

NQF has identified care coordination as a "priority area." NQF has endorsed a standard definition of care coordination and a framework for measuring it, but to our knowledge has endorsed only one specific standard for care coordination.13/ We request that CMS encourage the development and endorsement of care coordination measures to address the areas that NQF has identified as essential, namely:14/

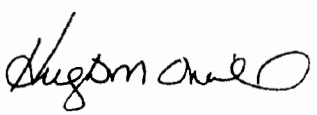
10/ NQF, Safe Practices for Better Healthcare: A Consensus Report at VII, http://www.qualityforum.org/ (last visited September 13, 2007).
11/ http://www.ntocc.org/
12/ 72 Fed. Reg. at 38200; 72 Fed. Reg. at 42801.
13/ NQF, *NQF-Endorsed™ Definition and Framework for Measuring Care Coordination* (May 2006).
14/ *Id.*

- Medical home for each patient;
- Proactive plan of care and follow-up for each patient;
- Use of standardized, integrated information systems;
- Standardized data elements for patient's personal medication record;
- Standardized data elements for medication reconciliation; and
- Standardized care guidelines for transitions between care settings that include medication reconciliation and care plan and communication plan between medical team members, patients, and caregivers.

III. Conclusion

We thank you for your consideration of these comments on the Proposed Rule and hope we can continue to work with CMS to advance Medicare beneficiaries' access to innovative and life-saving therapies. Please contact me or Jon Spear, Associate Vice President, Federal Government Affairs, at 202-628-0500 if you have any questions or if we can be of further assistance on these issues. Thank you for your attention to these important issues.

Respectfully Submitted,



Hugh O'Neill
Vice President, Market Access and
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September 14, 2007

VIA COURIER

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
445-G, Hubert H. Humphrey Building
Washington, D.C. 20201

Re: CMS 1392-P

Dear Mr. Weems:

ISTA Pharmaceuticals is an ophthalmic pharmaceutical company whose products include therapies for inflammation, ocular pain, glaucoma, allergy, dry eye, and vitreous hemorrhage. One of our products is Vitrase® a preservative free ovine hyaluronidase that is primarily used as a spreading agent for anesthetics during ophthalmic surgery, most commonly cataract surgery. Use of Vitrase® speeds the process of anesthesia allowing the surgery to proceed more quickly and safely. Vitrase® is one of several hyaluroindase products on the market. These products are "substitutable" in the sense that they are clinically identical in terms of safety and effectiveness for their labeled indications and physicians and facilities choose one hyaluronidase product to use for each procedure.

We are concerned about proposed treatment of hyaluronidase products under the outpatient prospective payment system ("OPPS") and the revised payment methodology for ambulatory surgical centers ("ASCs") for CY 2008. We appreciate the opportunity to comment on the proposed rule and to bring those concerns to your attention.

Specifically we recommend that the Centers for Medicare & Medicaid Services (CMS):

- Eliminate pass-through status for recombinant hyaluronidase ("Hylenex" is the only commercially available recombinant hyaluronidase) because it does not meet the regulatory criteria to be recognized for pass-through payment,
- Package payment for J3473 "hyaluronidase, recombinant" into the payment for the ophthalmic services with which it is used, consistent with packaging proposals for other items such as contrast media and diagnostic radiopharmaceuticals and to assure that all hyaluronidase products used for ophthalmic surgery are treated similarly, and
- Continue to make separate payment for high concentration vials of hyaluronidase which are used for other procedures such as epiduralysis for pain management.

These recommendations will assure that the payment policies for hyaluronidase in OPPS and ASCs will better conform to existing OPPS regulations and CMS' goals for packaging costs under both the OPPS and ASCs. It will also avoid increased costs to beneficiaries and the program and avoid an inadvertent competitive disadvantage created by paying separately for one hyaluronidase product while payment for other products is packaged into the payment for the procedure.

Hyaluronidase Use

Hyaluronidase is a spreading or diffusing substance, which modifies the permeability of connective tissue through the hydrolysis of hyaluronic acid. Hyaluronidase temporarily decreases the viscosity of the connective tissue or "cellular cement" and promotes diffusion of injected drugs. Hyaluronidase may be either animal-derived (e.g., from cows or sheep) or a human recombinant product. Internal ISTA data indicates that 90 percent of hyaluronidase is used in ophthalmic surgery, primarily cataract surgery.

Hyaluronidase was developed in 1949. The Food and Drug Administration ("FDA") first evaluated and confirmed hyaluronidase for use in 1970. Wydase®, a bovine hyaluronidase, was available until 2001 when its manufacturer stopped production. Between 2001 and 2004, commercial hyaluronidase products were not available in the United States.[1] FDA approved two hyaluronidase products in 2004 and two more in 2005. All hyaluronidase products currently available have the same FDA approved indications, contraindications, and warnings. The approved indications are:

- As an adjuvant to increase the absorption and dispersion of other injected drugs;
- For hypodermoclysis; and
- As an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

All hyaluronidase products currently on the market have used 505(b)(2) applications to obtain FDA approval, meaning that the applications rely on data that were not developed by the applicant. The 505(b)(2) approval pathway under the Federal Food, Drug and Cosmetic Act ("FFDCA") allows products to reference data on safety and efficacy from other similar products thereby reducing the need for sponsors to develop and submit their own clinical data. FDA allows sponsors to do this when sponsors can show, among other things, that their product is identical to products previously on the market. This is what has happened in the case of all currently marketed hyaluronidase products including recombinant hyaluronidase. Therefore, the labeled indications for all hyaluronidases are identical and there is no evidence showing that one product is safer or more effective than another.

[1] Food and Drug Administration, "FDA Approves Vitrase® (Hyaluronidase for Injection)", *FDA Talk Paper*, May 6, 2004. (accessed on September 9, 2007 at http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01287.html)

Differences between products are found in the source of the product, its purity and the number of units per vial (the per unit activity is the same for all products), and whether a preservative is used in its manufacture. The chart below shows the products currently in the marketplace and their associated HCPCS codes. Vitrase® is the only ovine hyaluronidase available and is the only product studied for ophthalmic clinical use. It is also the only product available in a larger vial size for non-ophthalmic uses.

Drug	Manufacturer	Year Approved	HCPCS	Average Sales Price
Vitrase® (ovine)	ISTA	May 2004 (6200 USP) December 2004 (240 USP)	J3472 J3471	$0.19 per unit
Amphadase (bovine)	Amphastar	October 2004	J3470	$0.16 per unit
Hydrase (bovine)	PrimaPharm	October 2005	J3470	$0.13 per unit
Hylenex (recombinant)	Baxter	December 2005	J3473	$0.40 per unit

ISTA estimates that 80 percent of hyaluronidase use is in ASCs which follow a wide range of protocols for use of hyaluronidase in ophthalmic surgery. Our customers report that the number of units of hyaluronidase used per procedures range between 30 USP to 240 USP. One scientific study has shown that the mean use of ovine hyaluronidase for 108 subjects was 92.5 USP[2] while another demonstrated the value of 50 iu of hyaluronidase in ophthalmic surgery.[3] Feedback from ASCs suggests the most popular dose of hyaluronidase in cataract surgery is 75 USP.

In addition to use in ophthalmic surgery, hyaluronidase is also used in certain pain management procedures, including epiduralysis, and may also be used in the treatment of some cancers to prepare (soften) tumors for the administration of chemotherapy. Epiduralysis requires between 1,500 and 3,000 USP per procedure. According to the code descriptors, larger doses of Vitrase® may need to be reported using both J471 and J3472. For example, to bill for a full 6200 USP vial, a hospital would bill six units of J3472 (ovine, per 1000 USP) and 200 units of J3471 (ovine, up to 999 USP).

Three of the four hyaluronidase products have similar average sales prices ("ASP") of between $.13 and $.19 per USP. The fourth product, Hylenex, has an ASP more than twice as much ($.40/USP).

[2] Donnenfeld, E.D., *et al.*, "Evaluation of Preservative-Free, Highly Purified Hyaluronidase Ovine (Vitrase®), 200 USP units/mL, as an Adjuvant to Increase the Absorption and Dispersion of Other Injected Drugs Prior to Ocular Surgery", 19th Annual Ophthalmic Anesthesia Society (OAS) Meeting, Chicago, IL, September 23-25, 2005.

[3] Dempsey, G.A., *et al.*, "Hyaluronidase and Peribulbar Block", British Journal of Anesthesia, 1997; 78:671-674.

Medicare Payment for Hyaluronidase

Most use of hyaluronidase has been in ASCs, where the current Medicare payment system does not make separate payment for drugs and biologicals. The ASC facility payment includes payment for any drugs administered during the course of a covered ASC procedure. CMS has revised that payment system as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and will use the same payment groups developed under the OPPS to pay ASCs. Importantly, beginning in 2008, Medicare will pay separately for drugs provided in an ASC that are integral to a covered ASC procedure if those drugs are also separately payable under the OPPS.

Under the OPPS, Medicare pays separately for drugs if their costs cross a per-day threshold. In 2007 the threshold is $55 per day and the proposed threshold for 2008 is $60. Payment for drugs with per-day costs below the threshold is packaged into the payment for the procedure with which the drug is used. In the proposed rule updating the OPPS for 2007, CMS indicated it did not have 2005 claims data for J3471 and J3472 to determine whether or not those codes crossed the cost per-day threshold. In the absence of data, CMS proposed and finalized a policy that packaged payment for J3471 and paid separately for J3472. Payment for J3470 was also packaged beginning in 2007. At the same time, as part of a quarterly update, CMS established a pass-through payment for recombinant hyaluronidase (Hyelenx), J3473, beginning January 1, 2007. CMS proposes to continue packaging the costs of J3470 and J3471 and to continue the pass-through status of J3473.

For 2008, CMS has indicated a strong general preference to pay separately for fewer items and services under the OPPS and is interested in recommendations for increasing packaging of procedures and, among other things, drugs. As part of achieving that goal, CMS proposed to package certain categories of items that in the past may have received separate payment because those items were ancillary and supportive to the procedure which they are performed. The categories proposed for packaging include diagnostic radiopharmaceuticals and contrast media. Proposed treatment of hyaluronidase codes for 2008 is shown below.

Code	Short Descriptor	Status Indicator	2008 NPRM Payment Rate
J3470	Hyaluronidase injection	N	--
J3471	Ovine, up to 999 USP units	N	--
J3472	Ovine, 1000 USP units	K	$133.77
J3473	Hyaluronidase recombinant	G	$.40

Making Separate Payment for Hyelenex Inadvertently Creates a Market Bias

By providing pass-through payments for recombinant hyaluronidase in the OPPS setting and making separate payment in the ASC setting while other products are packaged, CMS has inadvertently created a market disadvantage for packaged products. Its proposed policy creates an incentive for hospitals to use the more expensive recombinant

product although there is no clinical evidence of a difference in its safety or efficacy. This situation is a prime example of concerns raised in 2005 by the Medicare Payment Advisory Commission (MedPAC).[4] More specifically, MedPAC was concerned that pass-through payments duplicate payments for costs already packaged into the procedure payment and unnecessarily increase program costs, beneficiary coinsurance, and the Part B premium.

This disadvantage will be exacerbated when CMS begins making separate payment for recombinant hyaluronidase in the ASC setting, the predominant site of service for hyaluronidase, next year. Historically, the ASC market for hyaluronidase has been extremely price sensitive due to the packaging of all drugs. The proposed CMS policy would create the opposite incentive by encouraging ASCs to use recombinant hyaluronidase.

The ASC rule states that CMS "will pay separately for all OPPS pass-through and nonpass-through drugs and biologicals that are separately paid under the OPPS[5]." We find this language ambiguous enough to be read as implying that CMS will make pass-through payments in the ASC setting. We are concerned about this for several reasons and would like CMS to clarify in the final rule that it is not making pass-through payments for drugs and biologicals in the ASC setting. Pass-through payments are specific to the OPPS and items qualify based on the relationship between their costs and the OPPS payment for relevant procedures. As shown below, drugs can qualify for pass-through payments with substantially lower costs based on comparison to the payment for procedures that are not ASC covered services. Congress specifically required pass-through payments for services provided in hospital outpatient departments but did not provide for similar payments to ASCs, even when mandating a change in the ASC payment methodology. In addition, while Congress held beneficiaries harmless from paying coinsurance on these payments under the OPPS, such protection will not apply to beneficiaries seen in an ASC. They must pay 20 percent coinsurance on all separately payable drugs including pass-through drugs.

In addition to our general concern about making pass-through payments in the ASC setting, we argue below that recombinant hyaluronidase does not meet the regulatory criteria to qualify for pass-through payments and should not have been granted pass-through status in the OPPS setting.

Recombinant Hyaluronidase is Ineligible for Pass-through Payments

As published in the OPPS regulations, for a drug or biological to qualify for pass-through payments the item must be considered to be both "new" and have "not insignificant costs". Recombinant hyaluronidase does not meet either of these criteria.

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[4] Medicare Payment Advisory Commission, Comment Letter on 2006 NPRM (CMS-1501-P), September 16, 2005. (Accessed on September 9, 2007 at http://www.medpac.gov/publications/other_reports/091605_OPPS_comment.pdf)

[5] See 42500 Fed. Reg. 72 (August 2, 2007)

Newness. For pass-through purposes, "new" is defined as being "first payable as an outpatient hospital service after December 31, 1996."[6] Hyaluronidase has been used as a spreading agent for more than 50 years. There is no reason to believe such use was not captured in the claims data utilized to establish the initial OPPS payment rates for ophthalmic procedures.

Further, as stated above, all the products currently on the market have used 505(b)(2) applications to obtain FDA approval, meaning that the applications rely on data that were not conducted by the applicant. The 505(b)(2) approval pathway under the Federal Food, Drug and Cosmetic Act ("FFDCA") allows products to reference data on safety and efficacy from other similar products thereby reducing the need for sponsors to develop and submit their own clinical data. FDA allows sponsors to do this when sponsors can show, among other things, that their product is identical to products previously on the market. This is what has happened in the case of all currently marketed hyaluronidase products including recombinant hyaluronidase (Hylenex). In fact, the only product which has been studied for safety and efficacy post approval is Vitrase®. Therefore, the labeled indications for Hylenex are identical to the labeled indications for Vitrase® and all other marketed hyaluronidases, and there is no evidence showing that Hylenex is safer or more effective than Vitrase® or any other hyaluronidase. Further, there is no reason to believe that Hylenex will be used for different off-label indications than Vitrase® (i.e., as a spreading agent with other procedures or in any other way).

Based on how FDA approved Hylenex and all other hyaluronidases, and the long history of using hyaluronidases in ophthalmic surgery, ISTA believes that Hylenex, although deserving of its own HCPCS code under the law, is not a new drug because it is clinically identical to products previously on the market (before 1996). For this reason, CMS should withdraw its pass-through status for Hylenex in CY 2008. However, even if CMS finds that Hylenex is a new drug, CMS should withdraw its pass-through status because it does not meet the "insignificant cost" test as discussed below.

Not Insignificant Cost Test. Costs are considered "not significant" if they meet all three of the following conditions:

> "(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.
> (ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.
> (iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service."[7]

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[6] 42 CFR 419.64(a)(4)(i)
[7] 42 CFR 419.64(b)(2)

In the 2001 interim final rule with comment, CMS indicated that if a drug met these criteria for any APC with which it might be billed, the drug could qualify for pass-through payments.[8] Such an approach is outdated in the current environment where drugs that do not qualify for pass-through payments must meet a per-day cost threshold for separate payment. Furthermore, the drug administration APCs, which could be billed with many drugs, have such low payment rates that drugs that do not meet the per-day cost threshold easily qualify for pass-through payments. For example in 2006 the simplest drug administration APC had a payment rate of $8.14. Any drug costing more than $.81 could qualify for pass-through payment under the assumption that it could conceivably be billed with this procedure code. This result is contrary to the intent of the pass-through statute, which limits pass-through payments to items with more significant costs, and to CMS' goal of expanding the payment bundle to include low-cost drugs.

Allowing drugs to qualify for pass-through payments based on the administration APCs is particularly problematic for drugs that are more commonly used in surgical procedures. Recombinant hyaluronidase presents a good example. ISTA understands that in assessing whether recombinant hyaluronidase met the "not insignificant cost" criterion CMS compared the estimated cost of the drug with the payment for procedures in the drug administration ambulatory payment classifications ("APCs") 0352 and 0353. Information available at the time of CMS's decision suggested hyaluronidase is most commonly used in surgical procedures that are not represented by codes in those APCs. For example, in a Talk Paper released in 2004, FDA stated "Hyaluronidase has been used most commonly in combination with local anesthetics in the setting of ophthalmic (eye) surgery."[9] The American Academy of Ophthalmology issued a Rapid Clinical Report in 2001 on response to the absence of hyaluronidase which stated "In 1986, hyaluronidase was reported in the literature to enhance the diffusion of ocular anesthesia, and since then, has been widely used in injections of local anesthesia for cataract surgery and other ophthalmic surgeries."[10]

We confirmed that hyaluronidase is rarely billed with drug administration codes by analyzing Medicare OPPS claims data. In 2006, the two codes for hyaluronidase products used in ophthalmic surgeries (J3470 and J3471) were billed less than 1 percent of the time with procedures in APCs 0352 and 0353. Instead they were billed roughly 90 percent of the time with ophthalmic procedures. There is good reason for this. It would be considered unbundling to report codes from APCs 0352 and 0353 (or any other APC for drug administration) in addition to codes for a surgical procedure when the drug being administered was integral to the surgical procedure. This is because payment for a surgical procedure includes payment for all items and services considered integral to the procedure. Drug administration codes should only be reported when the drug administration is a separately identifiable service and unrelated to the surgical procedure.

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[8] 65 FR 67806

[9] Ibid.

[10] American Academy of Ophthalmology, "Adverse Effects Associated with the Absence of Hyaluronidase in Anesthesia for Cataract Surgery", Rapid Clinical Report, February 13, 2001. (Accessed on September 9, 2007 at http://www.eyeanesthesia.org/pdf/Wydase_Study_(21301).pdf)

APC	APC Name	2006 Payment Rate	Percentage of 2006 Claims	
			J3470	J3471
0352	Level I Injections	$8.14	<1%	0
0353	Level II Injections	$23.31	<1%	<1%
0246	Cataract Procedures with IOL Insert	$1,387.71	71%	77%
0672	Level IV Posterior Segment Eye Procedures	$2,194.61	21%	11%

Covance/Arent Fox analysis of 2006 OPPS claims data

The estimated average cost of recombinant hyaluronidase is $60 (150 USP at $.40/USP). The estimated average cost is only 4.3 percent of the payment for APC 0246 in 2006. When the most likely use of the product is the measure of comparison, recombinant hyaluronidase does not meet the first condition for pass-through payments.

Since recombinant hyaluronidase does not meet the newness criteria and does not pass the not insignificant cost criteria, it should not have pass-through status. In the absence of pass-through status, payment for J3473 recombinant hyaluronidase should be packaged with the payment for the ophthalmic procedures with which it is billed.

If CMS determines that the Pass-through Status of Hylenex Should be Continued then a Payment Offset Should be Established

Recombinant hyaluronidase does not meet the criteria for pass-through status under the OPPS. However, if such status is retained in 2008, the separate payment should be offset by amount included in the APC payment for the other hyaluronidase products. Such offset is required by statute[11] to avoid overpayment for costs already reflected in the APC rates. A weighted average of the price per unit for the three animal derived products suggests that the price per unit of recombinant hyaluronidase should be reduced by at least 43 percent. CMS has well established policy for offsetting transitional pass-through payments for medical devices and it should establish a similar policy for pass-through drugs and biologicals.

Payment for Ophthalmic Uses of Hyaluronidase Should Be Packaged

Because J3473 should not have pass-through status and claims data is not yet available on use of this code, CMS will have to determine whether recombinant hyaluronidase should be packaged or paid separately. We believe CMS should package all ophthalmic uses of hyaluronidase, including the recombinant product, into the APC payments for the relevant surgical procedures. This approach creates the most equitable result and is consistent with other CMS policies and goals:

- It applies the same payment status for the most common uses of clinically identical products and avoids giving any one product a competitive advantage based on packaging status. In the past, CMS has strived to achieve equitable

[11] 1833(t)(6)(D)(i)

treatment of similar products when some fall below and others are above the packaging threshold, such as in the case of oral anti-emetics.

- Unlike the treatment of oral anti-emetics, which are all paid separately, packaging all hyaluronidases would be consistent with a key CMS goal of increasing the bundle of services paid for under the OPPS and generally packaging more items and services into the APC payment for a procedure. It is consistent with CMS's proposal to package all diagnostic radiopharmaceuticals and contrast agents with their related procedures even though some products are above the packaging threshold. Specifically, the proposal to package all contrast agents is practically identical to our recommendation. In the case of contrast agents, making separate payment for more expensive contrast agents provides an incentive for hospitals to use those agents which increases total costs to Medicare, increases beneficiary coinsurance and encourage inefficient use of hospital resources.
- It is consistent with the 2007 packaging of Vitrase® in the absence of OPPS claims data on J3471.

In the proposed rule for 2007, CMS used an estimated average dose of 150 USP to determine whether payment for J3471 should be packaged. Using this same average, recombinant hyaluronidase would not cross the packaging threshold at the payment rate of average sales price + 5 percent (the proposed payment rate for separately payable drugs).

Estimated Per-Day Costs for J3473	
ASP+6	$.40
ASP+5	.3962
Per-Day Costs (150 USP)	$59.43

However, we believe the assumption of 150 USP for per-day administration for ophthalmic procedures is incorrect. As noted Donnenfeld *et al.* found that the average administration of ovine hyaluronidase was 92.5 units.

ISTA also analyzed Medicare claims data to determine the average number of units of hyaluronidase billed per patient per day. In order to do this ISTA contracted with Covance Market Access Services to analyze data from the 2006 Medicare Hospital Outpatient Prospective Payment System public-use claims file. Covance's analysis found this distribution of billed services units for the 9,684 claims billed with J3471 in 2006:

HCPCS	Minimum	25th Percentile	Median	75th Percentile	Maximum
J3471	1	19	50	200	4080

The mean number of billed service units for J3471 claims is 124.82. Claims analysis for J3470 was not helpful because the code descriptor requires reporting of 1 vial (which equals one unit) no matter how many units from the vial are actually administered.

Therefore, the clinical literature and the Medicare claims data both show that the number of units of hyaluronidase used per procedure is far less than 150. No matter which number of units (92.5, 50, or 125) CMS uses to make its estimate of the total cost of Hylenex per-day, the number will always come out to less than $60.

Due to its clinical similarity to Vitrase® and other hyaluronidases, it is appropriate for CMS to assume that the number of units of Hylenex used per procedure will be the same as the number of units of Vitrase® (or any other hyaluronidase) used per procedure. This is because the activity of Hylenex on a per unit basis is the same as the activity of Vitrase® and other hyaluronidases so there is no reason to expect physicians would need to use more Hylenex per procedure.

Like the other hyaluronidase products used for ophthalmic purposes, the per-day costs of recombinant hyaluronidase can be assumed to be below the packaging threshold of $60. Payment for J3473 should be packaged in 2008.

Non-ophthalmic Uses of Hyaluronidase Should Continue to Be Paid Separately

Packaging ophthalmic uses of hyaluronidase would address payment for the most common and consistent uses of these products. Variability of dosage is within a limited range (75-240 USP), and the cost of the drug relative to the total procedure is small. Separate payment for other uses such as in pain management should be maintained. The quantity used is more substantial (1500 – 3000 USP for epiduralysis), and the cost is more significant relative to the total payment for the procedure. J3472 should remain unpackaged and edits should be established to allow J3471 to be paid separately when it is billed on the same claim with J3472. This would allow CMS to make payment for the total amount of hyaluronidase administered when it is used for non-ophalmic procedures such as epiduralysis. When a complete 6200 unit vial of Vitrase® is used, the correct way to report it is six units of J3472 and 200 units of J3471. Because the total amount used per day exceeds $60, the entire amount should be paid, not only the portion reported under J3472. Although, CMS has appropriately determined that the per-day costs of non-ophthalmic uses of hyalruonidase are greater than the packaging threshold and has provided separate payment for J3472, without an edit that allows J3471 to also be separately paid in this circumstance, hospitals and ASCs cannot receive payment for the full amount of hyaluronidase used in those procedures. Claims processing edits are necessary to fully reflect the costs incurred by hospitals and ASCs for those procedures.

Summary

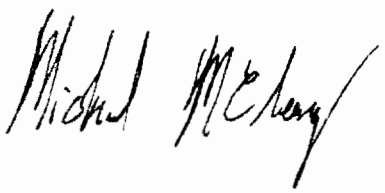
We recommend;

- Eliminating pass-through payments for recombinant hyaluronidase (J3473),
- Packaging payment for J3470, J3471, and J3473 into the payment for the ophthalmic procedure with which they are used,
- Continuing to make separate payment for J3472, and

- Making separate payment for J3471 when it is billed with J3472 through creation of an edit to allow CMS to recognize and pay for the total amount of the drug administered.

Packaging ophthalmic uses of hyaluronidase meets CMS goals for increased packaging and equitable treatment of similar products. Such approach avoids creating inadvertent competitive disadvantages and produces incentives for hospitals to provide efficient care. Thank you for your consideration of these recommendations.

Sincerely,



Michael McCleerey
Director of Marketing

cc: Elizabeth Richter, CMM
Carol Bazell, CMM

CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

Henry H. Kramer, Ph.D., FACNP
Executive Director

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September 14, 2007

Via Hand Delivery, UPS, and Email

Mr. Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stop – C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1392-P

Comments on CMS Proposed Rule on Hospital Outpatient Prospective Payment System for 2008

Radiopharmaceuticals and Nuclear Medicine

Dear Mr. Kuhn:

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is pleased to submit these comments to the Centers for Medicare and Medicaid Services on the proposed changes to the Medicare hospital outpatient prospective payment system (HOPPS) for 2008. 72 Fed. Reg. 42,628 (Aug. 2, 2007). CORAR has worked closely with CMS since the inception of HOPPS in 2000 to develop and refine APCs and payment methodologies that support appropriate hospital use of radiopharmaceuticals and high quality care for Medicare patients.

Radiopharmaceuticals offer physicians valuable tools in the diagnosis and treatment of Medicare patients with a wide array of serious cardiac, neurological, oncology, pulmonary, kidney, and other diseases. We express our thanks to CMS for its efforts to recognize the unique clinical and cost features of radiopharmaceuticals in the development of the HOPPS system and urge that CMS not package diagnostic radiopharmaceuticals, but rather move forward with more accurate payment methodologies for these important specified covered outpatient drugs. Below, we present a summary of our primary recommendations, then a more detailed analysis.

I. Summary

A. Concerns

1. CMS' proposal to package diagnostic radiopharmaceuticals into the nuclear medicine procedure APCs is seriously flawed for the following reasons:

    a. CMS' reliance on hospital claims data fails to accurately capture the hospital's average acquisition costs for most radiopharmaceuticals.

    b. Proposed payment levels will create improper financial incentives for quality care.

    c. Packaging radiopharmaceuticals disrupts the clinical and resource homogeneity of the nuclear medicine procedure APCs.

    d. Packaging radiopharmaceuticals violates the two-times rule.

    e. Packaging radiopharmaceuticals improperly subjects these drugs to wage index adjustments.

B. Summary Recommendations

1. CMS should continue to pay for diagnostic and therapeutic radiopharmaceuticals separately from the nuclear medicine procedures.

2. CMS should ensure that separate Medicare payment for radiopharmaceuticals accurately reflects the average acquisition cost, based on one of the following methodologies:

    a. Manufacturer or nuclear pharmacy reported estimated average acquisition cost (EAAC) or average sales price (ASP), including the costs of overhead and pharmacy handling for radiopharmaceuticals. These data could be available in 2008 for some therapeutic and some high cost diagnostic radiopharmaceuticals. Methodologies need to be developed along with legal clarifications with respect to manufacturers obtaining data from nuclear pharmacies to estimate acquisition costs or average sales prices.

    b. Hospital reporting of radiopharmaceutical invoice prices on claims submitted to Medicare contractors and calculation of average acquisition costs based on reported invoice pricing.

3. CMS should edit/trim hospital reported claims data, to ensure that acquisition costs for radiopharmaceuticals and related services are

appropriately captured for all radiopharmaceuticals and nuclear medicine procedures. Even edits and trims may not correct data for the highest cost therapeutic radiopharmaceuticals, which may require separate price or cost reporting.

II. Detailed Analysis

This section presents CORAR's detailed analysis of CMS' proposed policy on HOPPS payment for radiopharmaceuticals.

A. Problems with Packaging Radiopharmaceuticals

1. Flaws in data/methods – deficient payment – tumor/infection imaging

CMS is relying on flawed data and questionable methodologies to propose packaging of radiopharmaceuticals into nuclear medicine procedure APCs. As one example, CMS is proposing to package four diagnostic radiopharmaceuticals into a newly structured APC 408 Level III Tumor/infection imaging APC. CMS proposes to pay for the packaged radiopharmaceuticals and the procedure at a rate of $1,022.88. The procedure and radiopharmaceutical mean costs range from $536 to $2,697. First, the CMS data on these four radiopharmaceuticals reflects an extremely wide range in acquisition costs, and CMS selection of data fails to reflect the average acquisition cost, plus overhead. Second, CMS' use of hospital data for packaging results in loss of data on radiopharmaceuticals that is needed for accurate payment.

The consequence of these flaws is a proposed payment level which:

a. Violates the statutory 2-times rule;

b. Disrupts the clinical and resource homogeneity in APC 408 and the other tumor/infection imaging APCs; and

c. Underpays the hospital for use of clinically appropriate radiopharmaceuticals, and overpays for other radiopharmaceuticals.

The details of the CMS data are presented in the attached chart.

Issues with CMS Proposed Bundling of Diagnostic Radiopharmaceuticals
For APC Advisory Panel
From CORAR
August 22, 2007

Radiopharmaceutical with 78804 (APC 408)	Tumor Type per Package Insert	Median Cost Simulation for Claims with Four Diagnostic Radiopharmaceuticals Proposed to be Bundled into APC 408 Level III Tumor/Infection Imaging					
		Number of Single Claims	Median Cost per Single Claim	Mean Cost Per Single Claim	Minimum Cost per Single Claim	Maximum Cost per Single Claim	Coefficient of Variation
78804 Only Line on Claim	N/A	93	364	537	47	5,539	114
A9507 - In111 capromab	Biopsy-proven prostate cancer, clinically-localized in patients at high-risk for pelvic lymph node metastasis. Post-prostatectomy patient with a rising PSA in whom there is a high clinical suspicion of occult metastatic disease.	56	1,277	1,994	571	10,270	91
A9542 - In111 ibritumomab dx	Part of therapeutic regime-in patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkins lymphoma	94	1,819	2,697	310	28,165	132
A9556 - Ga67 gallium	Demonstrate the presence and extent of Hodgkins disease, lymphoma, and bronchogenic carcinoma. May be useful as an aid in detecting some acute inflammatory lesions	114	457	536	142	2,223	68
A9565 - In111 pentetreotide	Primary and metastatic neuroendocrine tumors bearing somatostatin receptors	377	1,305	2,268	251	14,386	113
Bundled Revenue Code Only (no other HCPCS on claim)	N/A	16	495	847	254	1,985	79
Other HCPCS Code	N/A	122	1,076	1,136	177	2,932	62
Total – All Single Major Claims	N/A	872	1,072	1,701	47	28,165	134
CMS Median Cost File Statistics	N/A	1,268	1,010	1,630	117	14,987	128

Minimum Median Cost per Case (78804 Only) **364**
Minimum Median Cost w Radiopharmaceutical on Claim **457**
Maximum Median Cost w Radiopharmaceutical on Claim **1,819**

Data Source: 2006 Medicare Outpatient claims as released in the 2008 OPPS proposed rule file.

Observations:

1. APC 408 contains only one procedure code - CPT 78804
2. Example of four different radiopharmaceuticals that were used with this one procedure code in the 2006 single claims data.
3. The median cost for single claims varies widely depending on the radiopharmaceutical used (coefficient of variation is 113.82)
4. Combined procedure and radiopharmaceutical mean costs range from $2,697 to $536.
5. APC 408 - Level III Tumor/Infection Imaging is proposed to be paid at $1,022.88

Methodology notes: This data is not wage index adjusted or trimmed, nor does it include pseudo-singles. This is the primary reason for the difference in our calculated values in row 11 versus CMS' numbers in row 13.

Presented by CORAR
Prepared by Cleverly + Associates

2. Similar/Additional Problems with Cardiac Imaging

CMS proposes to package not only three radiopharmaceuticals into the cardiac imaging APCs, but also the cardiac imaging add on procedures. Further, CMS proposes to collapse the three cardiac imaging APCs into two APCs, and move essentially all the cardiac procedures into Level I leaving just one procedure (CPT 78465) in Level II cardiac imaging. The proposed packaging of cardiac imaging agents and add on procedures would create new APCs that ignore significant clinical and resource differences within the broad family of nuclear cardiac imaging. Such packaging results in violations of the two times rule.

- Edit claims data and put CPT 93017 on By-Pass List

Consistent with recommendations by the APC Advisory Panel (September 6, 2007), CMS should edit the hospital claims data to ensure that all claims used to determine payment for nuclear medicine APCs and radiopharmaceuticals are complete and accurate. One specific example would be to put CPT code 93017 (cardiovascular stress test) on the by-pass list. This procedure is typically performed with myocardial perfusion SPECT procedures (CPT 78465), which is proposed for a single procedure APC. CMS' exclusion of multiple procedure claims results in a serious loss of representative data which could be "recovered" if CPT 93017 was put on the by-pass list. Including a larger body of hospital claims data for CPT 78465 would significantly correct payment for proposed APC 377, especially in light of CMS' proposal to bundle a number of add-on procedures, as well as radiopharmaceuticals into APC 377.

The chart attached at the end of this letter demonstrates how putting CPT 93017 would enlarge the base of claims and improve the accuracy of the payment for both cardiac imaging APCs.

3. Radiopharmaceuticals qualify for separate payment as SCODs

CMS suggests that radiopharmaceuticals can be packaged because they are diagnostic supplies. We respectfully disagree. The Medicare HOPPS statute recognizes radiopharmaceuticals (both diagnostic and therapeutic) as specified covered outpatient drugs. See Social Security Act § 1833(t)(14)(B)(i)(I). This section of the HOPPS statute provides no legal basis for CMS to treat radiopharmaceuticals differently than other specified covered outpatient drugs. CMS should continue to pay separately for diagnostic radiopharmaceuticals.

Other sections of the Medicare HOPPS statute similarly classify radiopharmaceuticals as drugs and do not give CMS any authority to package. See, for example, § 1833(t)(6)(A)(iii) recognizing radiopharmaceuticals as qualifying for drug pass through payment. We object to CMS' suggestion that radiopharmaceuticals are supplies. Both Medicare statutes and FDA regulatory authorities treat all radiopharmaceuticals as drugs. Furthermore, there is no statutory or regulatory basis

for distinguishing diagnostic from therapeutic radiopharmaceuticals. All should be paid separately.

Additionally, CMS has introduced a new concept that diagnostic radiopharmaceuticals are incidental and ancillary to the nuclear medicine procedure and function effectively as supplies. See 72 Fed. Reg. at 42737. There is no authority for CMS to bundle drugs that are incidental or ancillary. CMS is also relying on a form of "functional equivalence" which is expressly limited by statute. See Social Security Act § 1833(t)(7)(F).

B. Problems with proposed payment levels for therapeutic radiopharmaceuticals

CORAR agrees that therapeutic radiopharmaceuticals, as CMS proposes, should be paid separately. CORAR expresses deep concern that the data and methods CMS uses to calculate payment levels for therapeutic radiopharmaceuticals, particularly, higher cost therapeutics fails to capture the drugs' average acquisition costs. Clearly, the proposed payment levels result from a number of problems including, for example charge compression. CMS proposes payment levels for some products especially those for the treatment of non-Hodgkins lymphoma (A9543 and A9545) which are so low that they risk hospital refusal to use the drugs because of seriously deficient payment.

Some therapeutic radiopharmaceuticals which qualify as drug regimens enable data reporting by the manufacturer if information can be obtained from the nuclear pharmacy that prepares, distributes, and prices the radiopharmaceutical to the end user. CORAR recommends that CMS accept either manufacturer or nuclear pharmacy reported estimated average acquisition cost (EAAC) or a related form of average sales price (ASP) for high cost therapeutic radiopharmaceuticals. In many cases, the preparation and distribution of therapeutic radiopharmaceuticals can allow the estimation of an average acquisition cost or the estimation of an average sales price and reporting to CMS by the manufacturer or the nuclear pharmacy. In some cases, data may need to be provided by the nuclear pharmacy to the manufacturer. These raise very significant legal, compliance, and contractual issues, which will take some time to clarify fully. Consistent with many of the principles of ASP reporting, sales to certain entities, such as 340B hospitals would be excluded from the estimates, while discounts would need to be included. Radiopharmacies or nuclear pharmacies have no independent statutory obligation to report to CMS or to manufacturers on any pricing or cost data. New arrangements may need to be established to generate or transmit needed data. This may pose unique issues in light of distribution, preparation, and delivery functions for radiopharmaceuticals. Many technical questions need to be resolved relative to the methodologies to determine EAAC and the application of ASP reporting to the different facts and circumstances for radiopharmaceutical estimated average acquisition costs or average sales prices.

C. Recommendations

1. CMS should continue separate payment for diagnostic and therapeutic radiopharmaceuticals.

2. Radiopharmaceuticals should be paid separately when they qualify at the threshold for separate drug payment.

3. CMS should pay for radiopharmaceuticals using data and methods that effectively generate an average acquisition cost, including overhead:

   a. Manufacturer or nuclear pharmacy reported estimated average acquisition cost or ASP, plus overhead/pharmacy handling costs for radiopharmaceuticals in 2008.

   b. Hospital reported invoice pricing on the claims form to the Medicare contractor that calculates average acquisition costs.

CORAR urges that these methods can be accomplished with rapid input from all stakeholders by January 1, 2008 for some therapeutic and some high cost diagnostic radiopharmaceuticals. Significant methodological and legal issues exist for manufacturers and nuclear pharmacies in beginning a process to capture and report a reasonable proxy for hospital average acquisition costs. Estimating an average acquisition cost by the manufacturer requires use of acquisition cost data and likely different estimation methods that could vary from radiopharmaceutical to radiopharmaceutical. We believe that such an approach can generate a more accurate payment level for therapeutic and some high cost diagnostic radiopharmaceuticals starting in 2008. Such an approach, however, does not equate to the precision now associated with reporting of average sales price for conventional drugs. Thus, additional protections and qualifications must attach to manufacturer or nuclear pharmacy that reports estimated average acquisition costs or average sales price.

CMS could continue the current utilization of the hospital charges reduced to costs as an interim payment methodology while details of the new approaches are finalized and implemented. CMS has acknowledged that the CCR methodology can serve as a proxy for average acquisition costs, plus overhead and this gives CMS another mechanism for payment during 2008.

4. CMS should create edits, as described above, and also edits to the utilized paid claims files for rate setting that ensure inclusion of a charge for the nuclear medicine procedure, as well as a charge for the radiopharmaceutical. CMS should put CPT code 93017 on the by-pass list.

5. CMS should be prepared when new radiopharmaceuticals are approved by the FDA to fully utilize the new drug pass through

authority to pay appropriately during the 2 to 3 year period, and acquire data that enables accurate payment based on average acquisition cost, plus overhead for new radiopharmaceuticals.

III. Conclusions

CORAR appreciates this opportunity to share its comments with CMS. We urge full consideration and implementation of our recommendations and welcome meeting with CMS again to discuss in greater detail how best to implement these recommendations to ensure high quality care for patients receiving radiopharmaceuticals under HOPPS.

Sincerely,

Lisa M. Saake

Lisa M. Saake, R.N, MBA
Co-Chair, Clinical Practice and Reimbursement Committee

Fred E. Longenecker

Fred E. Longenecker
Co-Chair, Clinical Practice and Reimbursement Committee

Cc: Carol M. Bazell, M.D. (CMS)
Kenneth A. McKusick, M.D., FACR, FACNP (Nuclear Medicine APC Task Force)

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Analysis of APC 377 - Level II Cardiac Imaging: Procedures billed on MMAJ Claims

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

Question: APC 377 includes one CPT® code: 78465. Why are <10% of occurences used in setting the payment rate?

From CMS Median Cost File

APC	Definition	SI	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0377	Heart image (3d) multiple	S	765.25	51,583	566,252	189.57	3035.09	843.58	755.79	48.16	9.1%

	Claim Type per CMS	Count	Percent
SMAJ	Single Major Procedure (all used for median cost calculation)	30,636	5%
MMAJ	Multiple Major Procedures (some used for median cost calculation)	535,434	85%
OBS	Observation (None used for median cost calculation and not in above table)	60,237	10%
Total	**Untrimmed total volume**	**626,307**	**100%**

Median cost is based on set of 30,636 SMAJ + 16,063 (3% of MMAJ) + set of MMAJ pseudo-singles with 93017 on different date of service.
Is it clinically realistic to perform procedure without a cardiovascular stress test?

Simulation of Median Cost if 93017 is added to bypass list (includes application of CMS cost trimming methodology and wage index adj):

APC	Definition	SI		Single Frequency	Total Frequency	Trimmed Minimum Cost	Trimmed Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0377	Heart image (3d) multiple	S		454,102	566,252	249.58	2840.44	909.96	840.39	41.26	80.2%

(Continued)

Summary of claims with multiple major procedures:

Other HCPCS on Claim with 78465	Definition	Procedure Type	HCPCS Appears on Bypass in Proposed Rule	Count of Claim Lines with Procedure	Percent of Claim Lines with Procedure (Procedures with >= 10% Listed)
78465	Heart image (3d), multiple	J	No	535,434	100%
93017	**Cardiovascular stress test**	**J**	**No**	**520,036**	**97%**
78478	Heart wall motion add-on	M	No	481,843	90%
78480	Heart function add-on	M	No	478,754	89%
A9500	Tc-99m sestamibi, up to 40 mCi	M	No	300,137	56%
A9502	Tc-99m tetrofosmin, up to 40 mCi	M	No	203,728	38%
84484	Assay of troponin, quant	B	No	185,385	35%
93005	Electrocardiogram, tracing	J	Yes	149,297	28%
82550	Assay of ck (cpk)	B	No	134,488	25%
36415	Drawing blood	B	No	130,922	24%
J0152	Adenosine injection, dx, 30 mg	M	No	129,504	24%
85025	Automated hemogram	B	No	117,470	22%
82553	Creatine, MB fraction	B	No	114,464	21%
A9505	Tl-201 thallous chloride, per mCi	M	No	103,713	19%
J1245	Dipyridamole injection	M	No	89,018	17%
G0378	Hospital observation per	M	No	87,650	16%
80048	Basic metabolic panel	B	No	78,515	15%
93307	Echo exam of heart	J	No	71,864	13%
93320	Doppler echo exam, heart	M	No	70,079	13%
93325	Doppler color flow add-on	M	No	69,920	13%
85610	Prothrombin time	B	No	69,056	13%
71010	Chest x-ray	J	Yes	65,010	12%
80053	Comprehen metabolic panel	B	No	64,261	12%
85730	Thromboplastin time, partial	B	No	59,629	11%
80061	Lipid panel	B	No	58,378	11%

Procedure Type Key:

J	Major Procedure
B	Bypass Procedure (Does not impact single status)
M	Minor Procedure (HCPCS code that has status 'N')
Blank	No HCPCS Code Present

Note: 'B' Indicator indicates fee paid item in CMS 2006 claims file.

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Analysis of APC 398 - Level I Cardiac Imaging

Note: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

From CMS Median Cost File

APC	Definition	SI	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0398	Level I Cardiac Imaging	S	346.52	40,207	82,718	43.14	9770.38	398.69	342.23	62.71	48.6%

Simulation of Median Cost if 93017 is added to bypass list (includes application of CMS cost trimming methodology and wage index adj):

APC	Definition	SI		Single Frequency	Total Frequency	Trimmed Minimum Cost	Trimmed Maximum Cost	Mean Cost	"True" Median Cost	CV	%Used in Median Cost Calculation
0398	Level I Cardiac Imaging	S		60,833	82,718	72.41	2561.16	509.01	432.65	62.26	73.5%

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We are smith&nephew

September 14, 2007

VIA ELECTRONIC FILING AND HAND DELIVERY

Mr. Herb Kuhn
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington DC 20201

RE: CMS-1392-P Revisions to the Hospital Outpatient PPS and 2008 Payment Rates

New CPT Codes 22526 and 22527 to be Classified into APC 51 and Added to ASC List

Dear Mr. Kuhn:

Smith & Nephew, on behalf of its hospital customers, is pleased to submit these comments on the 2008 Proposed Hospital Outpatient Prospective Payment System ("HOPPS") Rule. We write to recommend that CMS place new CPT codes 22526 and 22527 into APC 51. This classification will establish appropriate reimbursement that reflects the procedure's cost, will allow physicians to make treatment decisions according to what is best for their patients, and will eliminate the current financial disincentives that prevent some hospital outpatient departments from offering this important procedure.

As you may know, effective January 1, 2007, the American Medical Association (AMA) established new Category I CPT Codes – 22526 and 22527 – for intradiscal electrothermal annuloplasty (IDET), a surgical spinal procedure for chronic discogenic low back pain in which a physician inserts a catheter into the intervertebral disc in order to deliver electrothermal heat. Previously, hospital outpatient departments recorded the performance of IDET with code 0062T. However, during its February 2006 meeting, the AMA recognized that a subset of the procedures then described by 0062T should graduate to Category I status. Today, 0062T describes percutaneous intradiscal annuloplasty, any method *except electrothermal*, while 22526 is used for percutaneous intradiscal *electrothermal* annuloplasty (i.e. IDET).

In last year's final HOPPS rule, CMS tentatively assigned 22526 and 22527 to APC 50, Level II Musculoskeletal Procedures, which has a proposed 2008

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reimbursement rate of $1,868. This is the same APC as IDET's former Category III code 0062T. However, hospital costs associated with IDET are considerably higher than the reimbursement offered by APC 50. As shown in the attached price list, the cost of the disposable catheter alone is approximately $1,800. Hospitals must also purchase capital equipment and supply operating room time, surgical supplies, and nursing staff.

We believe that APC 51, Level III Musculoskeletal Procedures, more accurately reimburses hospital outpatient departments for IDET. Other procedures in this APC involve performance of similar clinical activities and require a similar commitment of hospital resources. This APC will neither under nor over reimburse hospitals for the procedure and will group IDET with several other procedures of the spine.

Thank you for this opportunity to comment on the 2008 Proposed HOPPS Rule. Like you, we value a Medicare Program that ensures patient access to all reasonable and necessary procedures. Hospital outpatient reimbursement that reflects the costs associated with IDET will allow patients who need this life changing procedure to receive it.

Sincerely,

Barbara Rohan

Barbara Rohan
Vice President of Government Affairs

Attachment: Price List

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U.S. Price List

IDET Spine Generator Equipment	Catalog #	Price
ELECTROTHERMAL™ 20S Spine System	7210644	$31,309[1]
Includes universal extension cable – 8 pin		

IDET Catheters and Needles

SpineCATH™ Intradiscal Catheter , 8 pin	7210440	$1,795[2]
SpineCATH™ XL Intradiscal Catheter , 8 pin	7210441	$1,795
SpineCATH™ Intradiscal Catheter , 4 pin	7209599	$1,795
SpineCATH™ XL Intradiscal Catheter , 4 pin	7209598	$1,795
Introducer Needle Gen. II	7209601	$69 each
Introducer Needle Gen. I	7209603	$69 each

[1] Generator has an expected life of three years after which replacement or significant software updates are required.
[2] Disposable Catheter – single use only. One or more catheters are used per procedure – Average is 1.5 per level.

NOVARTIS

Barbara Washington
Vice President Health Policy

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September 14, 2007

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments to The Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-1392-P)

Dear Acting Administrator Weems,

Novartis appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center (ASC)Payment System and CY 2008 Payment rates (CMS-1392-P) proposed rule (hereafter referred to as the "proposed rule"). Novartis is a leading global pharmaceutical manufacturer that is dedicated to the discovery, development and marketing of innovative products to cure diseases, to ease suffering, and to enhance the quality of life. Novartis manufacturers both traditional pharmaceuticals and physician administered drugs and biologics, many of which are utilized under the Medicare Part B benefit. In addition to our traditional pharmaceutical business, Novartis Vaccines and Diagnostics, created in 2006 following the acquisition of Chiron Corporation, offers products that prevent over 20 viral and bacterial diseases and is currently pursuing clinical research for over ten different pipeline products. Novartis Vaccines maintains the world's fifth largest vaccine business and is the world's second largest manufacturer of flu vaccines, as well as important meningococcal, pediatric, adult and travel vaccine franchises.

General Comment

The proposed rule references CMS' desire to increase packaging of multiple interrelated services into a single payment as a way to encourage providers to furnish services in the most efficient and cost effective manner. We are concerned that in many circumstances packaging may not take into account all the products and services needed in a specific procedure or treatment. Packaging supplies and services may undermine a physicians' ability to deliver the best care and will encourage provision of care based on reimbursement available.

HOPPS Comments

Pass-through Drugs

We support CMS' decision to continue its policy of paying for pass-through products under ASP + 6% with quarterly updates.

Specific Covered Outpatient Drugs

In the proposed rule, CMS continues its policy of setting payments for separately paid "specific covered outpatient drugs and biologicals" (SCODs), as defined in the Medicare Modernization Act (MMA), based on mean cost findings for each product. In this proposed rule CMS proposes the rate to be ASP +5%. The Social Security Act (SSA) requires that payment for SCODs in CY 2006 and subsequent years be equal to the "average acquisition cost for the drug for that year as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005.[1] We are concerned that ASP +5% will not provide adequate reimbursement for overhead cost. CMS did not make its methodology used to reach ASP +5% clear and we are concerned that payment is not adequate for facilities to provide access to SCODS.

Novartis is concerned that CMS did not adopt the recommendation of its own APC Panel. In the APC Panel's March 2007 report they state CMS should "implement a three-phase plan to address OPPS payment for pharmacy overhead costs. The first phase involves CMS working with interested stakeholders to develop a system of defining pharmacy overhead categories that require different levels of pharmacy resources and providing payment for these costs through New Technology APCs. The second phase involves a review of pharmacy overhead costs as identified by the GAO and MedPAC and other potential stakeholders. The third phase calls for specific billing of pharmacy overhead cost using HCPCS codes, corresponding to the categories developed in phase one, with payment rates developed from submitted hospitals claims data. The APC panel recommended that the overhead payments be made in addition to the current ASP+6 percent payment for separately billable drugs and biologicals.

In addition, as stated in our 2006 comments, it appears that the MedPAC "survey" which CMS relies upon to support its position that payments made at charges reduced to costs would be adequate, does not properly construe costs and charges. MedPAC stated that "hospital officials and others told MedPAC staff that hospitals build handling costs for drugs, biologicals, and radiopharmaceuticals into the charges for the products themselves as part of the markup over costs."[2] If true, this would assume that handling costs are already reflected in the hospital charges that CMS utilized. For these reasons, we believe that a more thorough and open examination of this issue should be held before any payment changes are proposed. Implementing the APC panel recommendations discussed above would provide the needed data to develop a payment system that would adequately reimburse pharmacy for material and overhead cost by providing payment aligned with the level of preparation, storage, transport and disposal cost required for specialized therapies.

At the same time CMS is proposing increased packaging and a reduction in payment to ASP+5%, the agency proposes that hospitals remove pharmacy overhead charges

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[1] SSA § 1833(t)(14)(A)(iii).

[2] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Ch 6, Payment for Pharmacy Handling Costs in Hospital Outpatient Departments," 141 (Jun. 2005).

(unpackaged) and report them on an uncoded revenue code line. This would have the effect of reducing reimbursement while increasing pharmacy billing cost to acquire the necessary data to provide adequate reimbursement for these services We encourage CMS to delay changing to an ASP+5% payment rate until CMS acquires the pharmacy overhead cost information through the implementation of the APC panel recommendations or a more thorough analysis of pharmacy overhead costs can be done and an appropriate pharmacy overhead payment process implemented in association with appropriate stakeholders.

ASC Comments

Novartis applauds CMS for establishing separate payment for billable drugs and biologicals in the Ambulatory Surgical Center payment system. CMS's decision to provide separate payment (unpackaged) for drugs and biologics utilized in the ASC will increase beneficiary access to appropriate therapy. Creating a coding and billing system that is parallel with HOPPS alleviates confusion and simplifies administrative burdens on practitioners.

We thank CMS in advance for its serious consideration of these comments and look forward to working with you to ensure accurate Medicare price reporting. Please feel free to contact me at 202-662-4378 if you have any questions regarding our comments or need additional information.

Sincerely,

Bonnie Washington
Vice President, Health Policy
Novartis Pharmaceuticals

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2007 SEP 14 P 2:46

September 14, 2007

Acting Administrator Kerry Weems
Office of the Administrator
Attention: CMS-1392-P
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Attention: CMS-1392-P

Re: CMS-1392-P; Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Issue Identifier: OPPS: Packaged Services (II. Proposed Updates Affecting OPPS Payments, A. Proposed Recalibration of APC Relative Weights, 4. Proposed Recalibration of APC weights, e. Service-Specific Packaging Issues)

Dear Acting Administrator Weems:

On behalf of Riverain Medical, I would like to express our appreciation for this opportunity to submit comments regarding the proposed Hospital Outpatient Prospective Payment System (HOPPS) for Calendar Year (CY) 2008 in the OPPS Packaged Services category. Riverain Medical is a healthcare company that offers chest radiography (CXR) computer-aided detection (CAD) hardware and software for early lung cancer detection. Specifically, our comments will focus on the payment rate for CXR CAD – Current Procedural Terminology (CPT) codes 0174T and 0175T – in the proposed HOPPS Rule for CY 2008.

Specifically, we are concerned that the proposed rule does not reflect a recent recommendation by the Advisory Panel on Ambulatory Payment Classification Groups (Advisory Panel) to provide a separate payment for CXR CAD. We agree with the Advisory Panel's recommendation and maintain that a separate payment for CXR CAD is consistent with other Medicare payment precedents. Moreover, we believe that the provision of such payment will increase access to CXR CAD, which in turn, will improve outcomes for Medicare beneficiaries and may be less costly to Medicare and the nation.

For your reference, I am attaching previous comments we have submitted to your agency with respect to separate payment for CXR CAD. We thank you in advance for your full and fair consideration of our views and stand ready to work with you and your colleagues to ensure that Medicare beneficiaries and their health care providers have access to CXR CAD in their communities.

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Lung Cancer Early Diagnosis and CXR CAD Background

As you may know, two-thirds of lung cancer patients are 65 years or older.[1] There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.[2] Patients who have smaller primary lung tumors at diagnosis have better clinical outcomes than patients with large tumors at diagnosis. One study found that approximately two-thirds of patients with early stage lung cancer present with pulmonary symptoms[3]. The authors concluded that "a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis." As such, early detection and diagnosis of lung cancer are essential to improved survival and outcomes.

CXR is currently the most frequently used test to detect lung lesions that are suspicious for lung cancer. The American College of Chest Physicians' guidelines recommend a CXR for patients with cough and risk factors for lung cancer or metastatic cancer. Unfortunately, CXR is a poor test for detecting cancers that are less than 14 mm in size. For example, one study found that radiologists missed 71%, 28%, and 12% of lesions $\leq$ 10 mm, 10-30 mm, and 30-40 mm, respectively. The authors estimate a 23% drop in five-year survival for those patients whose lung cancers were missed.[4]

Another study indicated that survival is correlated with pathological stage (pStage) of detection. Five-year survival rates (in parentheses following the pStage) decreased as the cancer size increased and the invasive characteristics increased. Survival rates dropped from pStage IA (67%), IB (57%), IIA (55%), IIB (39%) to the largest and most invasive pStage IIIA cancers (23%)[5]. A recent study, based on the California Cancer Registry, indicates nearly five times the survival rate for those treated stage I patients, compared to those refusing treatment.[6] Therefore, a diagnostic tool that can detect lung lesions when they are small in diameter at an early pathological stage and are treatable should result in better outcomes for affected patients.

Riverain's CXR CAD technology is a Food and Drug Administration (FDA) premarket application (PMA) approved diagnostic tool available to help radiologists detect early stage lung cancer. CXR CAD is used by the radiologist separately from and after s/he interprets the chest x-ray; it identifies regions of interest on CXRs that may represent nodules, which could be early-stage lung cancer. CXR CAD helps to identify patients who are most likely to benefit from further work-up; potentially avoiding additional and/or more expensive tests. Ultimately, because CXR CAD is able to identify patients who may benefit most from chest CT, CXR CAD use may result in an increase in true positives found on chest CT scans and a

[1] Age-Specific Incidence of Lung Cancer, Environmental Protection Agency.
[2] Mery, C.M., Pappas, A.N., Burt, B.M., et al. Diameter of non-small cell lung cancer correlates with long-term survival implications for T stage. *Chest, 2005*(128), 3255-3260.
[3] Christensen ED, Harvald T, Jendresen M, et al. :The impact of delayed diagnosis of lung cancer on the stage at the time of operation. *European Journal of Cardio-thoracic Surgery* 12 (1997), 880–884.
[4] Quekel L, Kessels A, Goei R, et al. Miss rate of lung cancer on the chest radiograph in clinical practice. *Chest*, 1999(115), 720–724.
[5] Mountain, C.E., Revisions in the international system for staging lung cancer. *Chest*, 1997(111), 1710-1717.
[6] Raz DJ, Jason A. Zell JA, Ou S-HI, et al. Natural History of Stage I Non-Small Cell Lung Cancer: Implications for Early Detection. *Chest* 2007;132;193-199.

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subsequent reduction in total chest CT scans performed to follow up on suspicious CXR findings.

Data submitted by Riverain Medical to the FDA[7] in order to obtain PMA approval show that use of CXR CAD for select patients results in a significantly higher sensitivity for lung cancer detection. CXR CAD has been found to help radiologists detect more than 20% additional cancers 9-14 mm. Studies at University of Chicago[8] and University of Maryland have shown that CXR CAD identified 37% of cancers, and 38% of patients, whose cancers were *not* detected by radiologists in clinical practice. These patients could have been diagnosed earlier with CXR CAD, and likely would have had better outcomes due to earlier detection of their disease.

We are concerned about reports from physicians and hospital administrators across the country that due to insufficient reimbursement, they are not able to provide CXR CAD to the patients in their communities. We believe this poses a serious threat to access to appropriate and necessary care for Medicare beneficiaries, and we urge CMS to provide a separate payment, which will help ensure the utilization of this potentially life-saving technology. Separate payment is necessary because analysis of the Median Costs for Hospital Outpatient Services data, provided with the proposed rule, indicates that:

- reasonable usage[9] will not drive the median to allow hospitals to recover their investment for the technology;
- a hospital can only expect to earn $2.36 per CXR in CY 2008, which is not enough to support the use of this important technology; and
- a hospital can expect to lose $0.49 on every procedure in APC0260, which prohibits a hospital from absorbing the cost of CXR CAD.

[7] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

[8] Li F, Engelmann R, Metz C, et al. Results Obtained by a Commercial Computer-aided Detection (CAD) Program with Radiologist Missed Lung Cancers on Chest Radiograph. *Radiology*, in Press, 2007.

[9] Riverain Medical expects the usage of CXR CAD to be less than 50% even if all appropriate chest x-rays were read with computer-aided detection for the following non-exhaustive reasons:

a. Portable chest x-rays are not suitable for CXR CAD,
b. Not all Medicare recipients are age-appropriate (some are too young, others are too old),
c. Some recipients are not eligible for surgical treatment, and/or
d. Not all recipients have symptoms or risk factors suggesting CXR CAD is reasonable.

The following table shows the increase in median as the percentage use of CXR increases:

CXR CAD Usage (%)	Reimbursement ($)	Increase in median ($)
0	46.23	0.00
10	46.72	0.49
20	46.72	0.49
50	47.08	0.85

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Riverain Urges CMS to Adopt Advisory Panel Recommendation

As noted above, on March 8, 2007, the CMS Advisory Panel voted affirmatively to recommend to CMS that it assign a "special" packaged code ("Q" status) to 0175T and provide a separate payment for CY 2008. We are concerned that in the proposed HOPPS rule, your agency has not adopted this recommendation. We urge you to include, in the final CY 2008 rule, this recommendation and also to extend it to 0174T. Specifically, we respectfully request that a separate payment of $15 be made for each use of CXR CAD, just as currently is the case with separate Medicare payment for mammography CAD.

We feel strongly that Medicare payment policies should not create barriers to access to much-needed technology for beneficiaries. Given that this new technology represents an additional cost to the hospital, above and beyond the cost of other radiology supplies and equipment, a payment rate of $15 will enable hospitals to be reimbursed for the cost of purchasing and using CXR CAD and help ensure beneficiary access to the technology.

Summary

We believe that the assignment of status indicator "Q" with separate payment of $15 for CPT codes 0174T and 0175T would help to create efficient and cost-effective delivery of this reasonable and necessary technology, which provides essential information to the treating physician to appropriately guide the further diagnosis, treatment, and management of a patient's lung cancer. Additional payment for CXR CAD will help ensure that Medicare beneficiaries and their health care providers have access to important new technology that can help detect lung cancer at its earliest stages. At $15, we feel the cost-effectiveness for CMS of CRX CAD use is very high; by helping to find solitary pulmonary nodules, the use of CXR CAD may reduce the utilization of more expensive technologies - diminishing patient exposure to radiation and reducing the stress and cost associated with another test. We believe that the utilization of CXR CAD will help preserve scarce health care resources and save lives.

We appreciate the opportunity to submit these comments. My staff and I would be happy to answer any questions you may have. I can be reached at 800.990.3387 or via mobile phone at 330.284.3264. Thank you again for your consideration of the provision of a separate payment for CXR CAD.

Sincerely,

Sam D. Finkelstein

Sam D. Finkelstein
President

Enclosure: January 22, 2007 Comment Letter

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January 22, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1506-FC; Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates - Final Rule

Dear Center for Medicare and Medicaid Services:

Riverain Medical appreciates the opportunity to submit these comments regarding the Outpatient Prospective Payment System (OPPS) Final Rule for Calendar Year (CY) 2007. Riverain Medical is a healthcare company that offers chest radiography (CXR) computer-aided detection (CAD) hardware and software for early lung cancer detection, which is PMA approved by the FDA. Riverain Medical is committed to being a leader and innovator in CAD and diagnostic technologies that significantly aid medical practitioners in the early-stage detection of diseases.

Riverain Medical is commenting on the proposed payment of CXR CAD in the final OPPS Rule for CY 2007. Under the final rule CXR CAD, described by Category III Current Procedural Terminology (CPT) codes 0174T and 0175T, will not receive a separate APC payment in CY 2007 because of CMS' decision to assign it a status indicator of "N." CMS also decided to bundle payment for CXR CAD into payment for APC 0260, Level I Plain Film Except Teeth.

Riverain Medical disagrees with CMS' decision to assign CXR CAD a status indicator of "N" and bundle it into payment for APC 0260 for CY 2007. CXR CAD should be assigned to APC 1492 with a status indicator of "S".

Background

For your convenience, the CPT codes are provided on the AMA web site (http://www.ama-assn.org/ama1/pub/upload/mm/362/07catiiicodes121506.pdf are:

> 0174T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation, and
>
> 0175T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.

Extensive data on the ability of CXR CAD to detect lung cancers from numerous studies was presented to the Advisory Panel on Ambulatory Payment Classification Groups (Advisory Panel). Having heard the evidence, the Advisory Panel voted that 0175T should be packaged

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with additional payment using a status indicator of "Q". However, the final minutes of the meeting indicate that the Advisory Panel's final recommendation was not to provide additional payment, and CMS accepted this final recommendation.

While we accept that the Advisory Panel recommended CMS assign status indicators of "N" to 0174T and 0175T for CY 2007, we respectfully disagree with their final recommendation and ask that CMS assign status indicators of "S" and place them in New Technology APC 1492 with a payment rate of $15. We maintain that a modest new technology payment under APC is consistent with payment precedents, will improve outcomes for Medicare beneficiaries, and may be less costly.

Summary of supporting rationale

We understand that this letter is long because of all the reasons that support our request for reassignment. Consequently, we summarize the key reasons to change CMS' decision below. Each point is addressed at length after the summary. The numbers match the section where the reason is addressed.

1. Third-party payers paid $27.00 for use of CXR CAD
   - Private payer payment of $27 is consistent with Medicare payment of $15.
2. The original vote by the APC panel on August 23, 2006 was to assign a "special" packaged code ("Q" status) to 0175T
   - "Remote" can be a different time, place, or physician.
   - Providers may not have "arrangements" for reimbursement for CXR CAD.
3. CXR CAD will *not* be reimbursed when bundled with chest x-ray by driving the median cost higher
   - The median will be increased only by $2.00 with 50% utilization of CXR CAD.
   - Riverain Medical is not promoting over-utilization of CXR CAD but CMS's decision may cause over-utilization in order to obtain reimbursement.
4. Continuous product improvement lowers false positives
   - Lower false positives should reduce the call back rate.
5. CT, MRI, and PET are expensive ways to detect lung cancer
   - CT, MRI, and PET could be used routinely when CXR CAD is not available.
   - CT, MRI, and PET will likely be used only when the radiologist using CAD suspects lung cancer.
   - CT, MRI, and PET payment for 2007 are $298, $349, and $855, respectively, based on the final rule.
   - The cost of CT screening is estimated to be $115 billion. The estimated cost of paying for the use of CXR CAD, which is not screening, is $250 million over 5 years and $1 billion over 10 years.
   - CT subjects patients to large amounts of radiation. CXR CAD does not add any radiation because it uses existing chest x-rays taken for medical reasons.
   - More lung cancers are detected from chest x-rays than from chest CT.

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- CXR CAD was proven to help radiologists detect more than 20% additional cancers 9-14 mm.

6. CXR CAD is a diagnostic tool, not a screening test
   - There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.
   - Riverain Medical's CXR CAD was developed and was shown, to help radiologists detect early stage lung cancer.
   - Studies show that CXR CAD identified 37% of cancers, and 38% of patients, whose cancers were *not* detected by radiologists in clinical practice. These results were reported by researchers at the University of Chicago and University of Maryland. These patients could have been diagnosed earlier with CXR CAD.
   - One study showed that approximately two-thirds of patients with early stage lung cancer present with pulmonary symptoms. The authors concluded that "a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis."
   - The American College of Chest Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer.
   - CXR CAD is a diagnostic tool that identifies patients who are most likely to benefit from further work-up; potentially avoiding a more expensive workup.
   - Therefore, CXR CAD should improve the early detection of lung cancer and the clinical outcomes for such patients.
   - CXR CAD is used by the radiologist separately from and after s/he interprets the chest x-ray.
   - CMS could establish reasonable coverage restrictions to limit the use of the technology, instead of not paying for its proper use.
   - The cost-effectiveness is very high for a $15 payment for CXR compared to using CT, MRI, or PET before further workup is indicated.

7. Use of CXR CAD *acts* like a prevalence screen and will therefore find lung cancers
   - Prevalence screens detect more lung cancers than incidence screens.
   - Chest x-rays are typically taken on different patients each year.
   - Therefore, use of CXR CAD is likely to be a highly effective and highly cost-effective way of detecting lung cancers in early stages in patients who are symptomatic *without screening*.

8. CXR CAD should *not* be bundled into the APC Payment for chest x-ray (APC 0260).
   - CMS policy is to bundle payments for two procedures when the resources used to provide those procedures cannot be distinguished.
   - If the median of APC 0260 drives reimbursement, then hospitals that use CXR CAD are penalized; those who do *not* are rewarded. Users need to buy separate equipment and thus have expenses related to its use.
   - $15 is 34.4% of $43.60, the payment for APC 0260 in 2007. This percentage is too high for hospitals to absorb.

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- Other radiologic procedures that are similar to CXR CAD are paid separately:
  - Three dimensional post-image processing,
  - Mammography CAD, and
  - Radiology guidance procedures.
- By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries.
- CXR CAD should be paid separately under OPPS as a matter of policy consistency.
- CXR CAD should be paid separately under OPPS as a matter of fairness.
- CXR CAD should be paid separately under OPPS to allow access to Medicare beneficiaries.

9. APC Assignment for CXR CAD

- CXR CAD is a new technology, has a CPT Category III code and should be assigned to new technology APC 1492, with a category "S" status indicator.

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Supporting Rationale

1. Third-party payers paid $27.00 for use of CXR CAD

Third-party payers paid $27 for the use of CXR CAD (via CPT code 0152T in CY2006)[1]. The payers represent approximately 60 million covered lives. Payment of $27 by third-party payers is consistent with a payment of $15 by Medicare.

2. The original vote by the APC Advisory Panel on August 23, 2006 was to assign a "special" packaged code ("Q" status) to 0175T

Riverain Medical is not certain how and why this APC Advisory Panel vote was overturned. However, based on the comments with the final rule, "They questioned the meaning of the word "remote" in the code descriptor for CPT code 0175T, noting that is was unclear as to whether "remote" referred to time, geography, or a specific provider. They thought it was likely that a hospital without a CAD system that performed a chest x-ray and sent the x-ray to another hospital for performance of the CAD would be providing the CAD service under arrangement and, therefore, would be providing at least one other service (chest x-ray) that would be separately paid." While all three conjectures are accurate, it is important to note that providers of CAD do not necessarily have "arrangements" to read CAD. The attached letter indicates that "arrangements" may not exist and reimbursement for the CAD reading is necessary to provide the service.

3. CXR CAD will not be reimbursed when bundled with chest x-ray by driving the median cost higher

We disagree with CMS's supposition, "To the extent that CAD may be more frequently provided in the future to aid in the review of diagnostic chest x-rays as its clinical indications evolve, we expect that its cost would also be increasingly reflected in the median costs for chest x-ray procedures." Chest x-rays make up 51% of the utilization of APC 0260. Consequently, even with 50% utilization of CXR CAD, only 25.5% of the APC class is affected. Using CMS data provided with the preliminary rule and a $15 payment amount the actual reimbursement changes according to the chart and numbers below, based on a simulation. In particular, note that with a 50% utilization of CAD on existing chest x-rays the hospital can expect to receive only $2; $1 for the CXR CAD and $1 for the 49% of other procedures in the APC. $9 is paid when 75% of chest x-rays are read with CAD. $14 is paid for 95% utilization. Riverain Medical is neither promoting over-utilization of CXR CAD nor screening; CXR CAD is not expected to have high enough utilization to materially affect the median. CMS policy of not providing separate payment may promote over-utilization in order to obtain reimbursement.

[1] *Aunt Minnie* October 24, 2006. Aunt Minnie is the largest and most comprehensive community Web site for medical imaging professionals worldwide.

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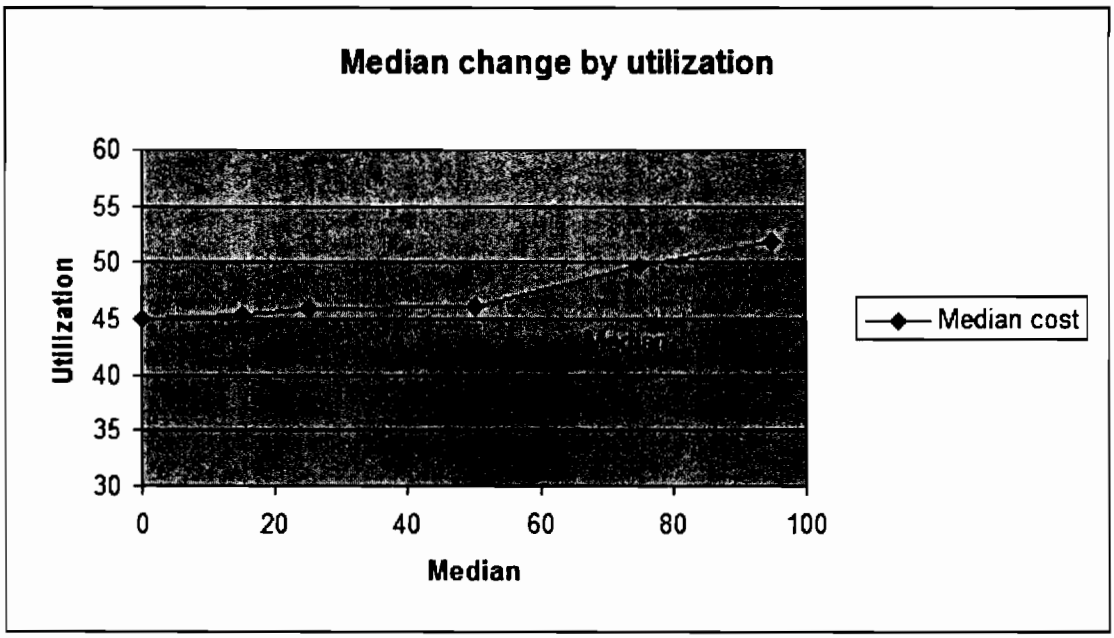

Hospital Analysis; Every procedure in APC 0260 is paid more when median increases

Example 1: 95% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$7	chest x-ray
Other APC 0260	49	$7	Other APC 0260
		$14	Total to hospital

Example 2: 75% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$5	chest x-ray
Other APC 0260	49	$5	Other APC 0260
		$9	Total to hospital

Example 3: 50% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$1	chest x-ray
Other APC 0260	49	$1	Other APC 0260
		$2	Total to hospital

* Note that % utilization refers to % of the APC group. The utilization of chest x-ray remains at 51% because Riverain Medical is *not* advocating screening. The examples given here change the usage of CXR CAD on the constant number of chest x-rays.

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4. Continuous product improvement lowers false positives

On November 1, 2006 FDA approved Riverain Medical's PMA supplement for the newest version of its CXR CAD, which lowers the false positive rate by 30%. This achievement should translate into fewer call backs for further work up.

5. CT, MRI, and PET are expensive ways to detect lung cancer

The results of a large collaborative study conducted by the International Early Lung Cancer Action Program (I-ELCAP) investigators were reported in the October 26, 2006 New England Journal of Medicine[2]. The investigators concluded, "We found CT screening for lung cancer to be highly cost-effective". However a study published in JAMA in 2003[3] indicated that "The total societal cost for an annual helical CT screening program of at-risk ever-smokers is very high. An estimated 50 million men and women in the United States are ever-smokers between the ages of 45 and 75 years. If 50% of this group received periodic annual screening, the program costs are approximately $115 billion (discounted) based on our study estimates." Compare that to the Congressional Budget Office's (CBO) estimate of the cost of CXR CAD, $250 million over 5 years and $1 billion over 10 years[4].

Another cost besides the dollar cost of finding lung cancer with CT screening is the radiation cost. Radiation causes cancer. CXR CAD does not add any radiation to that of the chest x-ray.

CXR CAD used on existing chest x-rays is a cost-effective alternative. More lung cancers were found on routine chest x-rays (101) than CT scan (32) in a retrospective chart review covering more than 5 years of lung cancer patients referred to the Weill-Cornell Medical College thoracic surgery service with biopsy proven non-small-cell lung cancer (NSCLC) who were asymptomatic at presentation[5]. Weill-Cornell Medical College is one of the ELCAP centers. The actuarial 5-year survival in the CXR group was 84% of stage IA, 55% for stage IB and 28% for all other stages combined. Unfortunately, only 39% of cancers in stage IA were found on chest x-rays. More lung cancers could have been found with CXR CAD because CXR CAD was proven to help radiologists detect more than 20% additional 9-15 mm lung cancers.[6] It makes more sense to allow CXR CAD to be used on chest x-rays than to subject patients to CT because CXR CAD costs less in dollars and in radiation exposure to patients. CMS can help the fight against lung cancer by providing a separate reimbursement for CXR CAD.

The cost for a CRX CAD image is too high for a hospital to absorb under the $43 payment obtained for an X-ray. Hospitals without CRX CAD are more likely to refer patients internally to a spiral CT, MRI, or PET scan if the diagnosis is uncertain. The payment for a CT (HCPCS 71275), MRI (HCPCS 71550), or PET (HCPCS 78811) are $298, $349, and $855, respectively. Contrast that with the situation that the physician chooses a CXR CAD image. S/he would

[2] The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006;355:1763-71.
[3] Mahadevia PJ, Fleisher LA, Frick KD, et al. Lung cancer screening with helical computed tomography in older adult smokers; A decision and cost-effectiveness analysis. *JAMA* 2003;289:313-322.
[4] Analysis by Congressional Budget Office November 2006.
[5] Altorki N, Kent M, and Pasmantier M. Detection of early-stage lung cancer: computed tomographic scan or chest radiograph? *J Thorac Cardiovasc Surg* 2001;121:1053-7.
[6] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

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simply refer the x-ray to a center that has that technology and let that center file for reimbursement.

6. CXR CAD is a diagnostic tool, not a screening test

There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.[7] Patients who have smaller primary lung tumors at diagnosis have better clinical outcomes than patients with large tumors at diagnosis. CXR is currently the most frequently used test to detect lung lesions that are suspicious for lung cancer. Unfortunately, CXR is a poor test for detecting cancers that are less than 14 mm in size. For example, one study found that radiologists missed 71%, 28%, and 12% of lesions $\leq$ 10 mm, 10-30 mm, and 30-40 mm, respectively. The authors estimate a 23% drop in five-year survival for those patients whose lung cancers were missed.[8] Another study indicated that survival is correlated with pathological stage (pStage) of detection where pStages IA, IB, IIA, IIB, and IIIA were associated with 67%, 57%, 55%, 39%, and 23%, respectively[9]. Therefore, a diagnostic tool that can detect lung lesions when they are small in diameter and in an early pathological stage should result in earlier detection and treatment of lung cancer. Riverain's technology for CXR CAD is a PMA approved diagnostic tool available for this purpose. Moreover, recent evidence has shown that early detection and treatment of lung cancer with chemotherapy is correlated with prolonged five-year survival rates.[10] The I-ELCAP investigators reported a 92% 10-year actuarial survival rate of patients with clinical stage I cancer who underwent surgical resection within 1 month after diagnosis[11]. The body of evidence indicates that CXR CAD should improve clinical outcomes for these patients.
CXR CAD identifies regions of interest on CXRs that may represent nodules, which could be early-stage lung cancer. It employs a multi-step image enhancement and analysis processing system that consists of a series of algorithms and classification technologies to identify regions that may contain indications of cancer and isolating them from the normal structure of the heart, blood vessels, ribs and other structures of the chest. The system includes digital image processing for noise reduction, image enhancement, anatomy segmentation, feature extraction, pattern recognition, neural network computing, and fuzzy logic.

A recent study conducted at the University of Chicago indicated that 37% of missed lung cancers could have been detected earlier if CXR CAD was used. Similarly, a recent study at the University of Maryland demonstrated that 38% of the patients with missed lung cancer could have been detected earlier if the x-rays were interpreted with CXR CAD.

One study showed that approximately 2/3 patients with early stage lung cancer present with pulmonary symptoms[12]. The authors concluded that, "...a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis." The American College of Chest

[7] Mery, C.M., Pappas, A.N., Burt, B.M., et al. Diameter of non-small cell lung cancer correlates with long-term survival implications for T stage. *Chest, 2005*(128), 3255-3260.
[8] Quekel L, Kessels A, Goei R, et al. Miss rate of lung cancer on the chest radiograph in clinical practice. *Chest*, 1999(115), 720-724.
[9] Mountain, C.E., Revisions in the international system for staging lung cancer. *Chest*, 1997(111), 1710-1717.
[10] Winton, T., Livingston, R., Johnson, D., et al. Vinorelbine plus cisplatin vs. observation in resected non-small-cell lung cancer. *N Engl J Med, 2005*(352), 2589-2597.
[11] The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006;355:1763-71.
[12] Christensen ED, Harvald T, Jendresen M, et al. :The impact of delayed diagnosis of lung cancer on the stage at the time of operation *European Journal of Cardio-thoracic Surgery* 12 (1997), 880-884.

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Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer[13]. Such patients with suspicious chest x-rays could benefit from CXR CAD.

CXR CAD is not a chest x-ray and is not a screening test. CXR CAD is not a screening test; it is a diagnostic tool that identifies symptomatic patients who are most likely to benefit from additional workup.

CXR CAD is performed separately from, and after, a CXR when there is a finding from the patient's history and physical (e.g., a smoker with bloody sputum) that indicates a high risk of lung cancer and/or the radiologist continues to be suspicious of lung cancer after interpreting the CXR. CXR CAD results in the production of new images, which must be read by a radiologist, in addition to the initial CXR images. Typically, the radiologist will review the CXR CAD images side-by-side with the CXR images in order to determine whether a lesion requires further work-up. CXR CAD independently identifies suspicious and/or subtle nodules the radiologist may have not seen on the CXR.

Data submitted by Riverain Medical to the FDA[14] in order to obtain PMA (premarket approval) shows that use of CXR CAD for select patients results in a significantly higher sensitivity for lung cancer detection. Ultimately, because CXR CAD is able to identify patients who may benefit most from chest CT, CXR CAD use may result in an increase in true positives found on chest CT scans and a significant reduction in total chest CT scans performed to follow up on suspicious CXR findings.

There is no basis for believing that CAD will increase the number of CXRs performed in the outpatient or office setting because CXR CAD is not a screening tool and is not applied "automatically" to screening CXRs. It should be applied only to CXRs suspicious for lung cancer on the basis of a high prior probability of lung cancer based on a patient's history or physical examination. Using CXR CAD for screening is not its proper use.

CMS is justifiably concerned about the impact of costs of new technology on the Medicare Trust Fund. We often heard behind the scenes that CMS is concerned that every lung X-ray will receive CRX CAD. We disagree. As an alternative to effectively making the technology non-covered for all indications through payment policy, CMS could establish reasonable payment and then have appropriate coverage restrictions to prevent inappropriate overuse of this technology. CMS may wish to consider the savings from avoiding substantially more expensive imaging modalities. At $15, the cost-*effectiveness* of CRX CAD is very high. Contrast that cost with the cost of CT, MRI, or PET.

Riverain Medical understands that Medicare does not pay for screening. Comparisons made in sections *§5. CT, MRI, and PET are expensive ways to detect lung cancer* (above) and *§7. Use of CXR CAD acts like a prevalence screen and will therefore find lung cancers* (below) should not be misconstrued to think that CXR CAD is screening. These comparisons are made to show that CXR CAD can be a cost-effective alternative to CT screening. Expected results would be that many lung cancers could be detected early at a fraction of the costs. Annual screening

[13] Kvale, P.A. Chronic cough due to lung tumors: ACCP evidence-based clinical practice guidelines. *Chest, 129*(1), 147S-153S, January 2006 Supplement.
[14] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

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with CT would find more lung cancers but at a much higher price, as discussed in §5. *CT, MRI, and PET are expensive ways to detect lung cancer.*

7. Use of CXR CAD acts like a prevalence screen and will therefore find lung cancers

The I-ELCAP study discussed above found 348 (84%) lung cancers on baseline (prevalence) screening. Only 64 (16%) lung cancers were found on annual (incidence) screenings. The use of CXR CAD on existing chest x-rays will be similar to prevalence screening because typically new (different) patients are x-rayed each year, not the same patient x-rayed at designated intervals. CXR CAD may be an effective alternative to instituting a costly CT screening program.

8. CXR CAD should not be bundled into the APC Payment for CXR

It is inappropriate to bundle payment for CXR CAD into the payment for CXR, APC 0260.
CMS policy is to bundle the costs of two procedures when the resources used to provide those procedures cannot be distinguished. For example, the vast majority of radiology related procedures with status indicator "N" are "injection" procedures (e.g., injection of contrast into a blood vessel) where the hospital also bills for the actual x-ray as well. It is extremely difficult, if not impossible, for the hospital or CMS to distinguish between the cost of the "injection" and the cost of the x-ray itself.

Bundling APC 0260 does not and is not likely to ever cover costs of CXR CAD. For those who use CXR CAD, cost is never recovered because it applies to only one procedure in the APC (CXR) and to a vast minority of those procedures. Costs will always be incompletely reflected in APC payment. A user of CXR CAD always ends up with incomplete reimbursement for expense of providing CXR CAD. In effect, those hospitals that do *not* use CXR CAD are rewarded while those that use CXR CAD are penalized. As discussed in §3. *CXR CAD will not be reimbursed when bundled with chest x-ray by driving the median cost higher.* An analysis of the utilization data that CMS provided with the proposed rule indicates that the median is not likely to be impacted unless CXR CAD is used in a very high percentage of chest x-rays. Riverain Medical does not expect that utilization of CXR CAD, if it is assigned a status indicator of "N," will ever be high enough to appropriately and adequately change the median cost of procedures in APC 0260.

Please note that $15.00, the requested payment amount, is 34.4% of $43.60, the payment for APC 0260 in 2007. 34.4% is a very high percentage of total payment. It is much higher than is typically associated with bundled procedures. In fact, CMS recognizes that low-cost new technologies should be paid separately because it established new technology APC's for that very purpose. Note also that $15.00 is consistent with payments by third-party payers, as discussed in §1. *Third-party payers paid $27.00 for use of CXR CAD.* The cost for a CRX CAD image is too high to absorb under the $43 payment obtained for an X-ray. Hospitals without CRX CAD are more likely to refer patients internally to a spiral CT, MRI, or PET scan if the diagnosis is uncertain. However, if the physician prefers a CXR CAD analysis, they would simply refer the x-ray to a center that has CXR CAD technology and let that center file for reimbursement.

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Separate resources are necessary for CXR CAD. The resources, including the staff and equipment needed to deliver CXR CAD, are completely different, and distinguishable from those required to perform a CXR. Specifically, CXR CAD requires special software, hardware, information systems, and information technology staff whereas taking a CXR requires an x-ray machine, a radiology technician, and software that is entirely different from CXR CAD software.

Furthermore, CXR CAD is not only performed separately from a CXR, but is performed, not infrequently, at a different time and/or location and/or by a different radiologist from the CXR ("remote"). Typically this happens when a CXR is obtained in the emergency department at one time with the interpretation performed (by a radiologist) at another time. The interpretation would include a recommendation that CAD be applied to the images. Subsequently, after discussion with the treating physician, CAD is ordered and applied to the original CXR images on a different day. In this situation it is appropriate for the hospital to bill separately for CAD because it is an entirely different procedure performed on an entirely different day from the CXR. This example illustrates that the resources required for CXR CAD are entirely different from the resources required for CXR and thus it is inappropriate to bundle payment for CXR CAD into payment for CXR.

The FDA recognized that CAD would be performed after reading the chest x-ray. The labeling for the device states, "The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph."

The American Medical Association (AMA) recognizes that CXR can be read remote from the chest x-ray and created CPT Code 0175T for that use.

Below are several examples of radiologic procedures that are similar to CAD yet paid separately:

- **Three-dimensional post-image processing** - CMS, in the OPPS final rule for CY 2006, announced it would make separate payment for CPT codes 76376 and 76377, "3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image post-processing on an independent workstation" (76376), and "requiring image post-processing on an independent workstation" (76377). These codes are used to report the use of image post-processing technologies similar to CXR CAD and, just like CXR CAD, the resources (e.g., the software, hardware, and staff time needed to apply computer algorithms to radiologic images) used to generate these new images are entirely different, and distinguishable from, the resources used to generate the original images (e.g., the CT scan). These technologies, like CXR CAD, generate new images that must be interpreted in addition to (i.e., side-by-side with) the original radiologic (or MRI) images. CMS assigned CPT codes 76376 and 76377 to APC category 0340 and 0282 with a payment rate of $37.51 and $37.81, respectively, for CY2007.

- **Mammography CAD** - Mammography CAD, CPT code 76082, Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography, is paid separately under OPPS. Because separate payment, at the same rate as under the Medicare Physician Fee Schedule (MPFS), is required by statute, the same policy should be applied to CXR CAD.

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- **Radiology "guidance" procedures** - CMS makes separate payment for radiology "guidance" procedures. These are procedures where radiology equipment such as a CT scanner is used at the time of a surgical procedure to help "guide" the surgeon to improve the outcome or reduce the risk of a procedure such as a tumor removal or biopsy. This policy exists because CMS recognizes that the resources used to provide "guidance" are different and distinguishable from the resources used to perform the surgical procedure.

By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries. CXR CAD represents an additional and non-reimbursable cost to the hospital above and beyond the cost of a CXR. If hospitals, especially rural and smaller community hospitals, are not paid separately for CXR CAD, they may be less likely to invest in this technology, thereby denying beneficiary access to CXR CAD. In addition, mammography CAD and three dimensional post-processing imaging are paid separately, creating an incentive for hospitals to provide those technologies but not CXR CAD. This is unfair and does not permit the marketplace to assess the true value of CXR CAD as it does for the other comparable technologies. Bundling creates an unfair playing field and does not allow the marketplace and the medical community to determine the value of CAD and make a judgment as to its relative costs and benefits. CMS should not substitute its own value judgment for that of the marketplace. More importantly, however, not having CXR CAD available may limit the quality of care afforded to patients who may have lung cancer. Please note that two-thirds of lung cancer patients are diagnosed at age 65 years old or older. Denying beneficiary access to CXR CAD is effectively delaying their chance of early detection and treatment (i.e., reducing their chance of surviving lung cancer).

CXR CAD should be paid separately under OPPS both as a matter of policy consistency and as a matter of fairness. Separate payment for post-processing technologies is consistent with current CMS policy and bundling is a deviation from that policy. CXR CAD is a new technology with its own Category III CPT codes and OPPS policy is to assign a payment amount to Category III CPT codes irrespective of their costs or clinical benefits.

9. APC Assignment for CXR CAD

A Payment of $15 should be made for CXR CAD. This technology represents a significant additional cost to the hospital above and beyond the cost of other radiology supplies and equipment. We propose that CXR CAD be placed in APC 1492 with status indicator "S", with a payment rate of $15. A payment rate of $15 will enable hospitals to be reimbursed for the cost of purchasing and using CXR CAD. Alternatively, we propose assigning a status indicator of "Q" to 0174T and 0175T in CY 2007 with a separate payment of $15. We would like to point out that in August 2006 the Advisory Panel on Ambulatory Payment Classification Groups initially voted to recommend a "Q" status for 0175T with additional payment for its use.

Conclusion

CXR CAD identifies regions of interest on CXRs that are suspected nodule sites, an important indicator of early lung cancer. For CY 2007, CMS gave CXR CAD a status indicator of "N" and bundled it into payment for APC 0260. Resources used to deliver CXR CAD are completely different from those required to perform a CXR. Riverain Medical disagrees with the Advisory

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Panel on Ambulatory Payment Classification Groups' final recommendation to assign CXR CAD technology a status indicator of "N" and bundle it into payment for APC 0260. We request, as a matter of policy consistency, fairness, and Medicare beneficiary access, that CMS make a separate payment for CXR CAD and change the status indicator of CPT code 0174T and 0175T in CY 2007 to "S" and assign it to APC 1492 with a payment rate of $15.

We appreciate the opportunity to submit these comments on the Proposed Rule CMS-1506-FC and would be happy to answer any questions you may have. I may be contacted at 800.990.3387 or my mobile phone at 330.284.3264.

Thank you for your consideration of separate payment for chest x-ray computer-aided detection.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

Sam D. Finkelstein
President
Riverain Medical

Attachment: Letter from Rocky Pahwa, CEO AZ-Tech Radiology & Open MRI

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AZ-TECH RADIOLOGY & OPEN MRI

Open MRI, MRA Ultrasound, CT, X-Ray, Bone Density, & Mammography

Date: December 18, 2006

To: Riverain Medical
3020 South Tech Boulevard
Miamisburg, OH 45342

Dear Riverain Medical,

I am willing to ask for coding and reimbursement guidance. My radiology group practices in a rural area of Arizona. None of the hospitals or physicians offices in our area offer computer aided detection (CAD) for chest x-rays. As you know, we offer CAD in our practice and we plan to offer CAD to the hospitals and physicians in our area who do not provide it.

These other providers will send us film or digital chest radiographs after they determine that CAD is medically necessary. Because the other providers do not want to enter into a business arrangement with us, we will bill Medicare and other payers for CAD while the other providers will bill for the chest film. The current CPT code for CAD is an add-on code, which means we will be unable to use it because we are not billing for interpreting the chest film. Please advise us on how we can bill for CAD under these circumstances. If we cannot be reimbursed for CAD then we will not be able to provide it.

Thanks,

Rocky Pahwa
CEO

ASTRO
American Society for Therapeutic Radiology and Oncology

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September 14, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates and Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Mr. Weems:

The American Society for Therapeutic Radiation and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates" published in the *Federal Register* as a proposed rule on August 2, 2007. Our comments focus on the following issues which are presented in the order in which they appear in the proposed rule: (1) APC relative weights and the bypass list; (2) packaged services; (3) new HCPCS and CPT codes; (4) the 2-times rule; (5) new technology APCs; (6) SRS treatment delivery services; (7) payment for therapeutic radiopharmaceuticals; (8) brachytherapy; (9) inpatient procedures; and (10) quality data.

I. APC Relative Weights - Bypass List (72 FR 42636)

CMS generally uses single procedure claims to set the median costs for APCs because of the difficulty encountered while ensuring that packaged costs are appropriately allocated across multiple procedures performed on the same date of service. For several years, CMS has used a list of codes that do not have significant packaged costs to be "bypassed" when determining which claims can be used to set the median costs. The effect is to convert multiple procedure claims to ''pseudo'' single procedure claims. By bypassing specified codes that do not have significant packaged costs, CMS is able to use more data from multiple procedure claims. The

[1] ASTRO is the largest radiation oncology society in the world, with more than 9,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly changing healthcare environment.

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use of a bypass list is critical to radiation oncology because most claims have more than one procedure code. Before the inclusion of certain radiation oncology services on the bypass list, the median costs for radiation oncology services were based on a small fraction of the total claims and the resulting APC payments were unstable and inaccurate.
CMS proposes to continue using the codes on the CY 2007 OPPS bypass list but to remove codes that are proposed for packaging for CY 2008 (see our comments on this proposal in the section that follows). CMS also proposes to remove codes that were on the CY 2007 bypass list that "ceased to meet the empirical criteria under the proposed packaging changes when clinical review confirmed that their removal would be appropriate in the context of the full proposal for the CY 2008 OPPS."

The following eight radiation oncology codes are among the codes proposed for deletion from the bypass list:

CPT Code	CPT Descriptor
77280	Therapeutic radiology simulation-aided field setting; simple
77285	Therapeutic radiology simulation-aided field setting; intermediate
77290	Therapeutic radiology simulation-aided field setting; complex
77295	Therapeutic radiology simulation-aided field setting; three dimensional
77332	Treatment devices, design and construction; simple (simple block, simple bolus)
77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)
77417	Therapeutic radiology port film(s)

By removing these codes from the bypass list, more claims will remain multiple procedure claims and fewer claims will be used for rate-setting. This is a step backwards for radiation oncology. We are particularly concerned about the effect of removing the therapeutic radiology simulation-aided field setting codes (77280-77295) on the high dose rate (HDR) brachytherapy codes (77781-77784) since these are often billed together. This change in the bypass list interacting with packaging Image Guided Radiation Therapy (IGRT) codes, which also appear on HDR brachytherapy claims frequently, results in fewer single claims being used and less accurate payment rates for HDR brachytherapy and other codes.

More specifically, for all HDR brachytherapy claims, 14% of the HDR brachytherapy procedures had a corresponding IGRT line, whereas only 2% of the claims used for rate-setting had IGRT packaged. Further, contrary to CMS' intention to create more pseudo single procedure claims as a result of packaging, for HDR brachytherapy procedures CMS is creating far fewer, a 14 percentage point drop from 62% to 48% of total frequency. We believe this drop can be attributed largely to interaction of the proposed packaging of guidance procedures and the proposed changes to the bypass list.

In the HDR brachytherapy example, two radiation oncology CPT codes (77280 and 77290) that often appear with the HDR brachytherapy codes were removed from the bypass list. When the

proposed CMS methodology is applied (including the packaging proposal described in the next section of our comments and the proposed changes to the bypass list), the number of pseudo single claims that CMS uses to set rates for the HDR brachytherapy codes decreases substantially. The packaged guidance procedures are needed for the HDR brachytherapy radiation treatment (77781-77784) and not for setting the radiation fields (77280 and 77290. An unfortunate consequence of removing these codes from the bypass list seems to be that the costs of the guidance are simply eliminated from many of the claims used to calculate the median costs.

As shown in the table below, when the IGRT costs are included in the calculation of the costs for HDR brachytherapy procedures (in accordance with the packaging proposal described in the next section of our comments), the average IGRT costs per HDR brachytherapy procedure range from $10.45 to $24.16. However, once both the new CMS packaging methodology and bypass list are applied, the allocated average IGRT costs over the family of codes drop to a range of $0.86 to $3.17, due to the fact that only 2% of the single claims have IGRT while 14% of the claims have IGRT on the same date.

CPT Code	**CPT Descriptor**	**Added Cost of IGRT Before Use of Revised Bypass List (All Claims)**	**Added Cost of IGRT After Use of Revised Bypass List (Single Claims)**
77781	Remote afterloading high intensity brachytherapy; 1-4 source positions or catheters	$ 24.16	$ 0.86
77782	Remote afterloading high intensity brachytherapy; 5-8 source positions or catheters	$ 10.45	$ 1.86
77783	Remote afterloading high intensity brachytherapy; 9-12 source positions or catheters	$ 13.12	$ 2.04
77784	Remote afterloading high intensity brachytherapy; over 12 source positions or catheters	$ 22.37	$ 3.17

We are troubled by the end result which is a drop in the APC payment rate for APC 313 *Brachytherapy* in 2008 from $789.70 to $739.46. This decrease is alarming because IGRT is packaged and the median cost has gone down. It would appear that those claims with IGRT are not becoming pseudo singles at least in part because the bypass list no longer includes important radiation oncology codes. As a result, the costs of the IGRT are not being included in the median costs of the codes assigned to this APC.

ASTRO requests that CMS not delete the eight radiation oncology codes listed on the first table in this section above from the current list of bypass codes. While these codes may not have met the empirical tests for inclusion on the bypass list, we believe there is minimal associated packaging with these codes and that a re-review by your clinical staff will confirm that their removal would <u>not</u> be appropriate in the context of the full proposal for the CY 2008 OPPS.

II. OPPS: Packaged Services

The proposed rule includes a variety of discussions and proposals related to expanded packaging of services under the OPPS. We will address three of these in this section of our comments.

1. Proposed Packaging of Guidance Services (72 FR 42654)

As an initial step toward creating larger payment groups for hospital outpatient care, CMS proposes to package payment for items and services in the seven categories into the payment for the primary diagnostic or therapeutic modality to which CMS believes these items and services are typically ancillary and supportive. CMS refers to the codes they are proposing to package as "dependent services" and uses the term "independent service" to refer to the codes that represent the primary therapeutic or diagnostic modality into which they are proposing to package payment for the dependent service.

One of the seven categories proposed for packaging are guidance services, specifically those codes that are reported for supportive guidance services such as ultrasound and fluoroscopy that aid the performance of an independent procedure. Table 8 of the proposed rule "Guidance HCPCS Codes Proposed for Packaged Payment in CY 2008" includes the following 5 radiation oncology codes that are used in Image Guided Radiation Therapy (IGRT):

CPT Code	CPT Descriptor
76950	Ultrasonic guidance for placement of radiation therapy fields
76965	Ultrasonic guidance for interstitial radioelement application
77417	Therapeutic radiology port film(s)
77421	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
77014	Computed tomography guidance for placement of radiation therapy fields

Because these dependent guidance procedures support the performance of an independent procedure and they are generally provided in the same operative session as the independent procedure, CMS believes that it would be appropriate to package their payment into the OPPS payment for the independent procedure performed. However, as CMS appropriately notes, guidance services differ from some of the other categories of services that they are proposing to package for CY 2008. Hospitals sometimes may have the option of choosing whether to perform a guidance service immediately preceding or during the main independent procedure, or not at all, unlike many of the imaging supervision and interpretation services, for example, which are generally always reported when the independent procedure is performed. Thus, hospitals have several options regarding the performance and types of guidance services they use.

CMS believes that hospitals utilize the most appropriate form of guidance for the specific procedure that is performed. Appropriately, CMS does not want to create payment incentives to use guidance for all independent procedures or to provide one form of guidance instead of another. Likewise, we do not believe CMS should create payment incentives to avoid the use of quality-enhancing services for financial reasons. CMS expects to "carefully monitor any

changes in billing practices on a service-specific and hospital-specific basis to determine whether there is reason to request that Quality Improvement Organizations (QIOs) review the quality of care furnished or to request that Program Safeguard Contractors review the claims against the medical record."

In the case of IGRT, we share CMS' concern about the potential impact of the proposed packaging to the quality of care. The use of IGRT is increasing within and across hospitals as the added benefits of more precise radiation therapy become more widely recognized. We are extremely concerned that the packaging of IGRT will hamper the adoption and continued use of this valuable service.

In addition, we are concerned that the proposed payments for radiation oncology services may not reflect the full costs of the packaged services. The proposed reduction in payment for APC 0313 Brachytherapy from $789.70 to $739.46 highlights our concerns. As shown in the table below, the claims for the family of HDR brachytherapy codes (77781-77784) that also have IGRT codes on the claims have average IGRT costs ranging from $73.59 to $213.32.

CPT Code	CPT Descriptor	Average IGRT Cost on Brachytherapy Claim
77781	Remote afterloading high intensity brachytherapy; 1-4 source positions or catheters	$ 213.32
77782	Remote afterloading high intensity brachytherapy; 5-8 source positions or catheters	$ 156.87
77783	Remote afterloading high intensity brachytherapy; 9-12 source positions or catheters	$ 73.59
77784	Remote afterloading high intensity brachytherapy; over 12 source positions or catheters	$ 120.83

Despite the packaging of IGRT into the HDR brachytherapy codes, the median costs of the APC decreased. This anomalous drop in median costs may relate to the elimination of certain radiation oncology codes from the bypass list. Regardless of the cause, to preclude separate payment for IGRT and then to decrease the payments for the services to which they are packaged is an unacceptable consequence of the CMS proposal.

Consistent with the recommendations of the APC Panel during their September 2007 meeting, ASTRO urges CMS to withdraw its proposal to package the IGRT codes 76950, 76965, 77417, 77421 and 77014.

2. Proposed Packaging of Diagnostic Radiopharmaceuticals (72 FR 42667)

CMS proposes to package payment for diagnostic radiopharmaceuticals into the payment for diagnostic nuclear medicine procedures for CY 2008 to encourage hospitals to use the most cost efficient diagnostic radiopharmaceutical products that are clinically appropriate. CMS identified

diagnostic radiopharmaceuticals as those Level II HCPCS codes that include the term "diagnostic" along with a radiopharmaceutical in their long code descriptors. The diagnostic radiopharmaceutical HCPCS codes proposed for packaged payment in CY 2008 are listed in Table 17 of the proposed rule. CMS inappropriately included in Table 17 the following two codes that describe critical components of radioimmunotherapy:

A9542 Indium IN-111 ibritumomab tiuxetan, diagnostic, per study dose, up to 5 millicuries
A9544 Iodine I-131 tositumomab, diagnostic, per study dose

Radioimmunotherapy is completely distinct from the broader class of radiopharmaceuticals which are generally used for medical diagnostic purposes. Radioimmunotherapy involves the combination of a monoclonal antibody and a radiation emitting molecule or isotope. The monoclonal antibody attaches to a specific molecule on the cancer cells and the isotope emits radiation to kill the cells to which the monoclonal antibody has attached. This revolutionary and underutilized therapy results in the killing of cancer cells while sparing normal tissue cells.

Two radioimmunotherapies have been approved by the FDA for the treatment of certain types of non-Hodgkin's lymphoma. The brand names are Zevalin and Bexxar. The monoclonal antibody in Zevalin is ibritumomab tiuxetan while the monoclonal antibody in Bexxar is tositumomab. These therapies differ from traditional chemotherapy in that the entire treatment takes place over 7-14 days in several steps that comprise a single therapeutic intervention as opposed to multiple repeated cycles with traditional chemotherapy

Zevalin and Bexxar therapies involve in part the intravenous administration of two distinct radiolabeled components on different days. The initial administration uses a lower level of radioactivity. It is used to assess the biodistribution of Zevalin or to calculate the therapeutic dose of Bexxar. For both products, a nuclear scan is performed after this administration; perhaps this is why CMS considers this component of therapy to be diagnostic. However, the scans are not truly diagnostic because the patient's diagnosis of non-Hodgkins lymphoma is already known. Rather, this component of radioimmunotherapy is an integral part of the FDA-approved therapeutic regimen. It represents the initiation of therapy, not the diagnosis of disease. The primary purpose of every component and step of radioimmunotherapy is therapeutic, not diagnostic.

Regardless of how the products are classified, the proposed packaging of this component of Zevalin and Bexxar therapies will result in grossly inadequate payment for the products. A nuclear medicine procedure used in the assessment of the biodistribution of Zevalin or in the calculation of the dose of Bexxar is 78804 *Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging.* The 2008 proposed payment for code 78804 is $1,022.88. However, the estimated hospital acquisition cost for the Zevalin code A9542 is approximately $2,800; for the Bexxar code A9544 it is approximately $2,600. Although packaging is intended to encourage hospitals to use the most cost efficient diagnostic radiopharmaceutical product that is clinically appropriate, for this patient population there are no other products available. With payment rates that will not cover even half the cost of the products, patient access to the radioimmunotherapy will be impeded, as hospitals may no longer be able to make this therapy available to Medicare beneficiaries.

We strongly urge CMS to withdraw its proposal to package codes A9542 and A9544. Additional comments regarding Zevalin and Bexxar are provided in section VII of our comments below.

3. Composite APCs - Prostate LDR (72 FR 42679)

To further address growth in the OPPS and create stronger incentives for efficiency, CMS proposes a new concept of "composite APCs" and proposes to create two such APCs in CY 2008. In a composite APC, Medicare would pay a single rate for a service which is described and reported with a combination of HCPCS codes on the same date of service (or different dates of service) rather than continuing to pay for the individual services under service-specific APCs.

The proposed rule says that composite APCs will be considered where the claims data show that combinations of services are commonly furnished together. CMS believes that composite APCs will enable use of more valid and complete claims data, create hospital incentives for efficiency, and provide hospitals with significant flexibility to manage their resources that does not exist when payment is made on a per service basis. The two composite APCs proposed for CY 2008 are:

1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC
2) Cardiac Electrophysiologic Evaluation and Ablation Composite APC

Our comments address the LDR prostate brachytherapy composite APC. LDR is a treatment for prostate cancer in which needles or catheters are inserted into the prostate, and then radioactive sources are permanently implanted into the prostate through the hollow needles or catheters. The needles or catheters are then removed from the body, leaving the radioactive sources in the prostate forever, where they slowly give off radiation to destroy the cancer cells until the sources are no longer radioactive. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles or catheters and application of the brachytherapy sources. LDR prostate brachytherapy cannot be furnished without the services described by both of these codes.

CMS proposes to create a composite APC 8001, titled "LDR Prostate Brachytherapy Composite," that would provide one bundled payment for LDR prostate brachytherapy when a hospital bills these two CPT codes as component services provided during the same hospital encounter:

— 55875 *Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy*; and
— 77778 *Interstitial radiation source application; complex.* These two CPT codes are assigned status indicator "Q" to signify their conditionally packaged status.

Hospitals that furnish LDR prostate brachytherapy would report CPT codes 55875 and 77778 and the codes for the applicable brachytherapy sources in the same manner that they currently report these items and services (in addition to reporting any other services provided), using the same HCPCS codes and reporting the same charges. CMS will require that hospitals report both

CPT codes resulting in the composite APC payment on the same claim when they are furnished to a single Medicare beneficiary in the same facility on the same date of service.

ASTRO is cautiously supportive of this proposal with the exception of the packaging of image guidance which we believe should continue to be eligible for separate payment as discussed in the previous section of our comments. Also, we believe this major change in the APCs must be closely monitored to be certain that access to this important therapy is not compromised by this change in payment policy. We recommend that CMS report back on this specific issue in the future.

III. OPPS: New HCPCS and CPT Codes (72 FR 42701)

CMS proposes to continue the policy of recognizing new mid-year Category III CPT that the AMA releases in January for implementation the following July through the OPPS quarterly update process. Five Category III CPT codes that were implemented in July 2007 are listed in Table 27 of the proposed rule. One of the five codes is the radiation oncology code 0182T *High dose rate electronic brachytherapy, per fraction* which is proposed for assignment to APC 1519 New Technology - Level IXX with a proposed payment rate of $1,750.

The new Category III code 0182T *High dose rate electronic brachytherapy, per fraction* was approved by the CPT Editorial Panel during their October 2006 panel meeting. The request for this new Category III code was submitted by ASTRO. At the time of our application, there were no CPT or HCPCS codes that described the delivery of HDR x-ray radiation therapy utilizing an x-ray tube. In our application, we explained that this technology utilizes electronically-generated photons, not radioactive isotopes and that it has different resource costs than the current high dose rate (HDR) brachytherapy codes listed in CPT which describe the delivery of HDR radiation therapy using a radioactive source and high dose rate afterloader.

The table below lists the APCs and proposed 2007 payment rates for the three major families of brachytherapy that are described in CPT (intracavitary radiation source application, interstitial radiation source application and remote afterloading high intensity brachytherapy):

APC	APC Title	Proposed 2008 Payment Rate
0312	Radioelement Applications	$534.48
0313	Brachytherapy	$739.46
0651	Complex Interstitial Radiation Source Application	$981.88

Please note that the proposed payment rate of $1,750 for CPT code 0182T *High dose rate electronic brachytherapy, per fraction* is more than three times the payment rate for APC 0312, more than double the payment rate for APC 0313 and nearly double the payment rate for APC 651. While we applaud CMS for promptly incorporating new technologies into the OPPS and we acknowledge the problems faced by CMS in establishing payment rates for new technologies for which no hospital charge data is available, we are concerned that the payment rate of $1,750

is excessive relative to these other brachytherapy services and that it will encourage the adoption of an emerging technology where the risks and benefits have not been clearly established.

While we cannot be certain of the charges that hospitals might submit and we have not done a formal analysis of the resource costs associated with 0182T *High dose rate electronic brachytherapy, per fraction*, we are confident that they should be more in line with the other brachytherapy codes.

For Category III codes that will be issued in the future, we also recommend that CMS contact the relevant physician specialty society regarding any OPPS issues related to the outpatient hospital coding and payment of the services and procedures described by these codes. We understand that CMS must sometimes act quickly and that the views of stakeholders other than physicians must be considered. However, we believe physician specialty societies are in a unique position to provide advice because of their technical expertise, their day-to-day interactions with patients and the absence of financial incentives under the OPPS.

IV. OPPS: 2 Times Rule (72 FR 42703)

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services.

APC 0664 Level I Proton Beam Radiation Therapy is included in Table 28 of the proposed rule "Proposed APC Exceptions to the 2 Times Rule for CY 2008." We support the CMS decision to make an exception to the 2 times rule for this APC since this therapy is offered in only two facilities in the country. However, because of our concerns over the proposed reductions in payment for proton beam radiation therapy, we compared the payment rates and median costs in 2007 for the codes that describe these services to the proposed payment rates and median costs that have been proposed for 2008. As shown in the table below, the payments are proposed to be decreased by 27 percent, consistent with a significant reduction in median costs.

HCPCS	Description	APC	Payment Rate 2007 Final	Payment Rate 2008 Proposed	% change	Median Cost 2007	Median Cost 2008	% change
77520	Proton trmt, simple w/o comp	0664	$1,161.29	$ 845.50	-27%	277.19	267.2	-4%
77522	Proton trmt, simple w/comp	0664	$1,161.29	$ 845.50	-27%	1154.52	835.04	-28%
77523	Proton trmt, intermediate	0667	$1,389.37	$1,011.71	-27%	1381.26	999.19	-28%
77525	Proton treatment, complex	0667	$1,389.37	$1,011.71	-27%	734.54	708.07	-4%

Proton beam therapy is another form of precise radiation treatment for cancer that minimizes damage to healthy tissue and surrounding organs. However, it is an extremely complex and expensive technology that is currently offered in only two hospitals in the United States. To our knowledge, the charges for proton beam therapy by these institutions have not been reduced. Consequently, we believe there may be an error in the underlying data or in the analysis of the median costs.

We ask that CMS re-check its calculations and make any necessary corrections in the final rule. If there is a valid reason, consistent with the CMS methodology of calculating median costs and APC payments that accounts for the decreased median costs we then ask that CMS take into account that for any service provided by only two hospitals, the payment rates for the service will be highly dependent on the idiosyncrasies of billing and charging practices of those two hospitals.

We believe that other major medical centers are considering or have committed to adding proton beam therapy to their arsenal of weapons for the treatment of cancer. A 27 percent reduction in payment will discourage if not eliminate the further adoption of this useful technology. We recommend that CMS maintain the current rates for APCs 0664 and 0667 for 2 to 3 years, pending the collection of additional charge data from other hospitals that will adopt this technology in the future.

V. Other Services in New Technology APCs (72 FR 42705)

There are five procedures currently assigned to New Technology APCs for CY 2007 for which CMS believes the data are now adequate to support their reassignment to clinical APCs. One of these is a radiation oncology related procedure: CPT code 19298 *Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.* For CY 2008, CMS proposes to reassign this procedure from APC 1524 New Technology - Level XXIV with a payment rate of $3,250 to APC 0648 Level IV Breast Surgery with a payment rate of $3,372.

ASTRO supports this proposal which also has the effect of placing the three surgical codes related to the placement of the catheters for breast brachytherapy (CPT codes 19296, 19297 and 19298) into the same APC.

VI. SRS Treatment Delivery Services (72 FR 42716)

The proposed rule includes a review of the complex history of the coding and APC assignments for this category of radiation oncology services. For CY 2007, the CPT Editorial Panel created four new SRS Category I CPT codes: 77371, 77372, 77373, and 77435.

Of the four CPT codes, CPT codes 77371 and 77435 were recognized under the OPPS effective January 1, 2007, while CPT codes 77372 and 77373 were not. CPT code 77372 has been reported under one of two HCPCS codes, depending on the technology used, specifically, G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session) and G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment). CPT code 77373 has been reported under one of three HCPCS codes depending on the circumstances and technology used, specifically, G0251 (Linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment); G0339 (Image-guided robotic linear

accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment); and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment).

CMS received requests from ASTRO and other stakeholders to recognize CPT codes 77372 and 77373 under the OPPS rather than continuing to use the current Level II HCPCS codes. CMS notes that the hospital claims data continues to reflect significantly different hospital resources that would lead to violations of the 2 times rule were they to reassign certain procedures to the same clinical APCs in order to crosswalk the CY 2006 historical claims data for the four G-codes to develop the median costs of the APCs to which the two CPT codes would be assigned if they were to be recognized. Therefore, CMS proposes to continue to assign HCPCS codes G0173 and G0339 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), HCPCS code G0251 to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), and HCPCS code G0340 to APC 0066 (Level II Stereotactic Radiosurgery, MRgFUS, and MEG) for CY 2008.

ASTRO remains opposed to the continued use of G codes when CPT codes exist that describe the same services. The existence of codes that describe the same services is extremely problematic for hospitals since not all payers recognize Medicare's temporary HCPCS codes. We recommend that APCs 0065, 0066 and 0067 be combined into a single APC containing the following codes:

CPT Code	CPT Descriptor
77372	Srs, linear based
77373	Sbrt delivery
95966	Meg, evoked, single
95967	Meg, evoked, each addÆl
95965	Meg, spontaneous
0071T	U/s leiomyomata ablate <200
0072T	U/s leiomyomata ablate >200

Based on the median costs of the codes currently assigned to this APC, we estimate the median cost of this collapsed APC would be approximately $2,618. We acknowledge that collapsing three existing APCs creates a violation of the 2 times rule. However, we believe an exception should be made since the services described by the current G codes are appropriately described by the new CPT codes. The advantages of our recommendation include a reduction in the number of APCs for SRS, thus providing more clarity to hospitals when billing for SRS and SBRT procedures. In addition, ASTRO believes our recommendation to use existing CPT codes whenever possible instead of G codes is similar to the recent APC panel recommendations made during the September 2007 panel whereby the Panel recommended the use of existing CPT codes for cardiac rehabilitation services instead of the CMS proposed G codes.

VII. OPPS: Payment for Therapeutic Radiopharmaceuticals (72 FR 42738)

In CY 2006 and CY 2007, non-packaged radiopharmaceuticals were paid based on a hospital's charge for each radiopharmaceutical agent adjusted to cost using each hospital's overall cost CCR. This has been considered an interim step while CMS collected better data and explored alternative payment methodologies for setting payment rates.

For the CY 2008 proposed rule, CMS proposes to package payment for all diagnostic radiopharmaceuticals (see our comments in section I. B. above on the adverse impact of this proposal on radioimmunotherapy). For therapeutic radiopharmaceuticals, CMS proposes that their CY 2008 payment be based on CY 2006 claims data. Costs would be determined using the standard OPPS rate-setting methodology of applying hospital-specific departmental CCRs to radiopharmaceutical charges and defaulting to hospital-specific overall CCRs if appropriate departmental CCRs are unavailable. Included on the list of therapeutic radiopharmaceuticals proposed for this payment methodology in CY 2008 are the codes for the "hot" doses of the radioimmunotherapy regimens, Zevalin and Bexxar. Our comments that follow address only these two products.

CMS believes that the CY 2006 claims data reflect both the radiopharmaceutical charge and associated overhead charges and asserts that setting CY 2008 prospective payment rates based on CY 2006 hospital claims data provides an acceptable combined proxy for average hospital acquisition costs and radiopharmaceutical handling. However, CMS acknowledges having received stakeholder reports that costs for the most expensive radiopharmaceuticals are understated in OPPS claims data and specifically invites comment on how the proposed CY 2008 OPPS payment rates for therapeutic radiopharmaceuticals compare with the acquisition and associated handling costs of an efficient provider.

While we do not have external data on hospital acquisition costs and the costs of radiopharmaceutical handling for Zevalin and Bexxar, we are confident that the proposed payments are grossly nonrespresentative and that CMS must make an exception to the proposed payment methodology or patients will not have appropriate access to these valuable therapies. To assess the reasonableness of the proposed payment rates, we looked to the published Average Wholesale Prices (AWPs) in the July 2007 RedBook. We acknowledge that AWPs may not be closely related to actual acquisition costs but it is the experience of our members that hospitals are unable to obtain significant rebates or discounts when acquiring these products. Thus, the actual acquisition costs are undoubtedly closer to the published AWPs than the proposed payment rates. We also looked to the published payments established by Medicare carriers for Zevalin and Bexxar "hot" doses when they are administered in physicians' offices. A comparison of the proposed OPPS payment, the AWPs and the carrier fee schedule amounts shown in the table below clearly indicate that the proposed payment rates will be insufficient to cover the hospitals' estimated acquisition costs (as reflected by the carriers' fee schedule amounts), let alone the compounding and handling costs associated with these complex products.

CPT Code	CPT Descriptor	Proposed CY 2008 Payment	July 2007 Red Book AWP	NHIC, Noridian & TrailBlazer Fee Schedules
A9543	Y90 ibritumomab, rx (Zevalin)	$12,030	$25, 239	$23,977
A9545	I131 tositumomab, rx (Bexxar)	$8,283	$24,102	$22,897

We note that in the proposed rule, CMS considered but rejected continuation of the current methodology of payments based on individual case charges reduced to costs using hospital-specific overall CCRs because of a belief that such cost-based payments do not provide appropriate economic incentives for efficiency. In the case of radioimmunotherapy, the proposed payment rates simply cannot be viewed as providing appropriate economic incentives for efficiency. On the contrary, they create a very powerful economic incentive not to use radioimmunotherapy. For patients with certain types of non-Hodgkins lymphoma, hospitals are likely to turn to traditional, but often less effective, chemotherapy because those drugs are reasonably paid at ASP + 6 percent.

To assure continued access to radioimmunotherapy by Medicare beneficiaries, we urge CMS to make an exception to its proposed payment policy for therapeutic radiopharmaceuticals and to continue in 2008 the current methodology of paying for Zevalin and Bexxar based on individual case charges reduced to costs using hospital-specific overall CCRs. We recognize this may be viewed as a temporary solution to a complex problem. However, it will provide another year to evaluate other options, including the use of the Federally-reported average manufacturer's prices (AMPs) when these prices become publicly available (late in 2008 or early in 2009) or the use of average sales price (ASP) data if the manufacturers of the products would agree to report this information. We note that all the products used in the complete Zevalin and Bexxar regimens have been assigned National Drug Codes (NDCs) to which Medicare prices could be assigned.

VIII. OPPS: Brachytherapy (72 FR 42747)

Section 1833(t)(2)(H) of the Act, as amended by section 107(b)(1) of the TRHCA, requires separate payment groups based on stranded and non-stranded devices on or after July 1, 2007. To implement this requirement, CMS created six new HCPCS codes to differentiate the stranded and non-stranded versions of iodine, palladium and cesium sources. These six new HCPCS codes replaced the three prior brachytherapy source HCPCS codes for iodine, palladium and cesium (C1718, C1720, and C2633), all of which were deleted as of July 1, 2007.

Because CMS is required to create separate APC groups for stranded and non-stranded sources and because the CY 2006 billing codes did not differentiate stranded and non-stranded sources, CMS proposes to make certain assumptions when they estimate the median costs for stranded and non-stranded (low activity) iodine-125, palladium-103, and cesium-131 based on the CY 2006 aggregate claims data. CMS proposes to calculate median costs for stranded sources based on the 60th percentile of the aggregate data and the 40th percentile of the aggregate data for non-stranded sources. The difference in the proposed payments for the codes is shown in the table below:

HCPCS Code	Long Descriptor	Proposed CY 2008 Payment Rate
C2638	Brachytherapy source, stranded, Iodine-125, per source	$42.86
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	$31.91
C2640	Brachytherapy source, stranded, Palladium-103, per source	$62.24
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	$45.29
C2642	Brachytherapy source, stranded, Cesium-131, per source	$97.72
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	$51.35

The increased payment for each of the sources may not seem significant on a per source basis but when the number of sources used per procedure is taken into account, the increased payment for stranded sources becomes significant, as shown in the table below.

Source	Increased Payment for Stranded, per Source	Total Increased Payment for Stranded, Assuming 50 Sources	Total Increased Payment for Stranded, Assuming 100 Sources
Iodine-125	$10.95	$547.59	$1,095
Palladium-103	$16.95	$847.50	$1,695
Cesium-131	$46.37	$2,318.50	$4,637

ASTRO acknowledges the statutory requirement to create separate APC groups for stranded and non-stranded brachytherapy sources. However, we are concerned that the extent of the increased payments may encourage the utilization of stranded sources for other than clinical reasons and create perverse incentives in the marketplace. ASTRO encourages CMS to consider a revision of the proposal to calculate median costs for stranded sources based on the 60th percentile of the aggregate data and the 40th percentile of the aggregate data for non-stranded sources so that payment rates in CY 2008 do not create such drastic payment differentials for brachytherapy sources in absence of claims data.

IX. OPPS: Inpatient Procedures (72 FR 42771)

During the March 2007 APC Panel meeting, CMS solicited input on the appropriateness of removing 13 procedures currently on the OPPS inpatient list because they widely performed on an outpatient basis. The APC Panel recommended that CMS remove the 13 procedures from the OPPS inpatient list for CY 2008 and assign them to clinically appropriate APCs as shown in

Table 56 of the proposed rule. Included in Table 56 is CPT code 61770 *Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source* which CMS proposes to assign to APC 0221 *Level II Nerve Procedures* with a proposed payment rate of $2,041.

ASTRO supports this proposal. APC 0221 *Level II Nerve Procedures* includes other procedures that are comparable clinically and whose resource costs should also be comparable, e.g., 61720 *Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus.* Because 2007 will be the first year for which payment will be made under the OPPS, we recommend that CMS re-evaluate the APC assignment for code 61770 when actual charge data becomes available.

X. Quality Data (72 FR 42799)

Under amendments to the Social Security Act made by section 109(a) of the MIEA–TRHCA, CMS is required to establish a program under which hospitals will report data on the quality of hospital outpatient care using standardized measures of care to receive the full annual update to the OPPS payment rate, effective for payments beginning in CY 2009. CMS refers to the program established under these amendments as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). These amendments are consistent with CMS plans described in the CY 2007 OPPS/ASC final rule.

In the proposed rule for CY 2008, CMS identifies 10 quality measures that are both applicable to care provided in hospital outpatient settings and likely to be sufficiently developed to permit data collection consistent with the timeframes defined by statute. These measures address care provided to a large number of adult patients in hospital outpatient settings, across a diverse set of conditions, and were selected for the initial set of HOP QDRP measures based on their relevance as a set to all hospitals.

In addition, CMS seeks public comment on 30 additional measures, which have been identified as hospital outpatient-appropriate measures and are under consideration for inclusion in the HOP QDRP measure set, for CY 2010 or subsequent calendar years. One of the potential indicators is "Radiation therapy is administered within 1 year of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer."

ASTRO strongly supports inclusion of this radiation oncology measure in the Hospital Outpatient Quality Data Reporting Program measure set. We believe this quality measure is critical to ensuring evidence-based and well-coordinated cancer care. This measure emphasizes the importance of coordinating patient transitions between surgeons and radiation oncologists and is consistent with well-established National Comprehensive Cancer Network clinical practice guidelines for oncology supporting the benefit of postoperative radiation in lowering local recurrence rates. This measure was also endorsed by the NQF on May 9, 2007.

This measure also addresses a key gap in care among breast cancer patients who too frequently do not receive the recommended adjuvant therapy following surgery. A study published in the June 20, 2007 *Journal of Clinical Oncology* by researchers at Mount Sinai School of Medicine

found that 34% of female breast cancer patients did not receive adjuvant radiation therapy because of a combination of system failures, surgeon perceptions, and non-adherence. Further, this study, funded by the Agency for Healthcare Research and Quality as well as the National Center for on Minority Health and Health Disparities, found that this gap in care is particularly pronounced in minority women.

We also believe this measure should be assigned a high priority because it is one of few measures that accounts for effective care coordination, which is vital in caring for cancer patients, and addresses the significant number of Medicare beneficiaries with breast cancer. Additionally, increasing performance on this measure is anticipated to narrow the gaps in care for minority women. According to the American Cancer Society, an estimated 178,480 new cases of invasive breast cancer are expected to occur among women in the United States during 2007. An estimated 40,460 women a year will die from breast cancer.

Furthermore, we would note that the AMA-PCPI Oncology Workgroup, which is co-hosted by ASTRO, has decided not to develop, through a consensus based process, a physician-level measure of radiation therapy post-breast conserving surgery, and thus this measure will be removed from the 2007 Physicians Quality Reporting Initiative. The workgroup felt that this measure is most appropriate at the facility level, as the gaps in care are typically related to systems failures. We are pleased that CMS included this measure in this proposed rule. ASTRO agrees with that decision and strongly recommends incorporation of this measure in the HOP QDRP in 2008. As physicians who provide radiation therapy for women with breast cancer, we believe including this quality indicator will help to ensure all Medicare beneficiaries with breast cancer are evaluated and offered the most appropriate therapy and will help to overcome the barriers and biases that lead to under use of this important therapy.

Conclusion

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Trisha Crishock, MSW, Director, Health Policy and Economics Department at (703) 502-1550.

Respectfully,

Laura Thevenot

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